



# REPORT

OF

# THE PHARMACEUTICAL ENQUIRY COMMITTEE

सत्यमेव जयते

MINISTRY OF COMMERCE & INDUSTRY  
GOVERNMENT OF INDIA

1954

PRINTED BY THE MANAGER, GOVT. OF INDIA PRESS, NEW DELHI  
DISTRIBUTED BY THE MANAGER OF PUBLICATIONS, DELHI, 1954



REPORT  
OF  
THE PHARMACEUTICAL  
ENQUIRY COMMITTEE



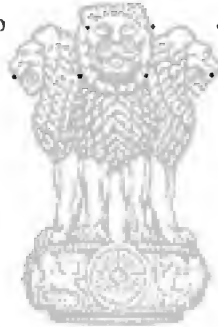
MINISTRY OF COMMERCE & INDUSTRY  
GOVERNMENT OF INDIA

1954



## PERSONNEL OF THE COMMITTEE

Major General S. L. Bhatia	. . . . .	<i>Chairman</i>
Dr. K. Vasudeva Rao	. . . . .	<i>Member</i>
Dr. B. B. Yodh	. . . . .	<i>Member</i>
Dr. J. C. Ghosh	. . . . .	<i>Member</i>
Dr. T. N. Banerji	. . . . .	<i>Member</i>
Dr. R. C. Shah	. . . . .	<i>Member</i>
Dr. T. R. Seshadri	. . . . .	<i>Member</i>
Dr. H. R. Nanji	. . . . .	<i>Member</i>
Shri K. R. Chandran	. . . . .	<i>Member</i>
Shri P. M. Nabar	. . . . .	<i>Member</i>
Dr. A. Nagaraja Rao	. . . . .	<i>Member</i>
Dr. B. Shah	. . . . .	<i>Secretary</i>



सत्यमेव जयते

## TABLE OF CONTENTS

	PAGES
<b>CHAPTER I—INTRODUCTION :</b>	<b>1—10</b>
(1) Appointment of the Committee	1—2
(2) Terms of Reference	2—3
(3) Previous Enquiries :	
Drugs Enquiry Committee, 1930; Panel on Fine Chemicals and Drugs & Pharmaceuticals, 1945; Panel for Pharmaceutical Industry, 1951; Planning Commission	3—6
(4) Present Enquiry :	6—10
Dates and Places of the meetings; Places visited; Associations and other bodies interviewed ; Questionnaires issued etc.	
(5) Report :	
Method of presentation	10
<b>CHAPTER II—PHARMACEUTICAL INDUSTRY, ITS SCOPE AND DEVELOPMENT :</b>	<b>11—87</b>
(a) ITS SCOPE AS UNDERSTOOD IN OTHER COUNTRIES AND IN INDIA :	11—15
(1) Early history	11
(2) Pharmaceutical Industry at present.	12—15
(b) DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY IN OTHER COUNTRIES AND IN INDIA :	15—19
(1) Pharmaceutical Industry in the U.K.	15—16
(2) Pharmaceutical Industry in U.S.A.	16
(3) Pharmaceutical Industry in India	16—19
(c) PRESENT POSITION OF THE INDUSTRY IN INDIA :	19—87
(1) Location	19—21
(ii) Government Factories :	22—60
(1) General ;	22—24
(2) Government Medical Stores Depot ;	25—30
(3) Opium Factory ;	30—35
(4) Penicillin Factory ;	35—37
(5) D.D.T. Factory ;	37—38
(6) Quinine Factories ;	38—50
(7) Shark Liver Oil Factories ;	50—55
(8) Other Government Institutions ;	55—60
(ii) Large Scale Private Enterprise under Foreign Control and/or Collaboration :	61—71
(1) Foreign Control	61—66
(2) Foreign Collaboration	66—71

	PAGES
(iii) Large Scale Private Enterprise under Indian Management :	71—77
(1) General :	71—73
(a) Manufacturers and/or processors of Drugs :	74—76
(1) Drugs of vegetable origin ; . . . . .	74
(2) Drugs of animal origin ; . . . . .	74—75
(3) Fine chemicals and synthetic drugs . . . . .	75—76
(b) Manufacturers of Disinfectants and Insecticides and their formulations . . . . .	76
(c) Manufacturers of Surgical Dressings . . . . .	77
(iv) Small Scale Private Enterprise : . . . . .	77—87
(1) General ; . . . . .	77—80
(2) Location ; . . . . .	80
(3) Products Manufactured ; . . . . .	80—81
(4) Staff & Testing Facilities ; . . . . .	81
(5) Scope for Improvement ; . . . . .	81—82
(6) Minimum Requirements. . . . .	82—87
<b>CHAPTER III—BASIC RAW MATERIALS AND PACKING MATERIALS OF THE INDUSTRY :</b>	88—115
(a) BASIC RAW MATERIALS OF THE INDUSTRY :	88—108
(1) General ; . . . . .	88
(2) Medicinal Plants ; . . . . .	88—91
(3) Ethyl Alcohol ; . . . . .	91—97
(4) Methyl Alcohol ; . . . . .	97—98
(5) Coal-tar Products ; . . . . .	98—106
(6) Animal Glands and Organs. . . . .	106—108
(b) PACKING MATERIALS OF THE INDUSTRY :	108—115
(1) Glass Containers . . . . .	108—114
Glass bottles, ampoules, vials etc.	
(2) Cork . . . . .	114—115
<b>CHAPTER IV—DEMAND AND PRODUCTION :</b>	116—133
(1) General ; . . . . .	116
(2) Essentiality of Drugs ; . . . . .	116—123
(3) Estimates of demand and steps necessary to meet them by increase in production ; . . . . .	123—132
(4) Cost of production and efficiency of process employed.	132—133
<b>CHAPTER V—STANDARDISATION, CONTROL OF QUALITY AND ADMINISTRATION :</b>	134—172
(a) PRESENT METHODS ADOPTED IN ADVANCED COUNTRIES :	134—146
(1) United Kingdom ; . . . . .	134—139
(2) United States of America ; . . . . .	139—143
(3) Canada. . . . .	143—146

(b) CONTROL OVER QUALITY OF PHARMACEUTICALS IN INDIA :	146—172
(1) Position till 1930 ; . . . . .	146—147
(2) Drugs Enquiry Committee ; . . . . .	147—149
(3) Drugs Act, 1940 :	
Its enactment ; Functions of the Central Government ; Functions of the State Governments ; Control over manufacture, sale and distribution ; Need for centralisation. . . . .	149—154
(4) Facilities for Testing of Drugs :	
Central Government Laboratories ; State Government Laboratories ; Manufacturers' Laboratories ; Public Analytical Laboratories. . . . .	154—160
(5) Menace of Spurious Drugs. . . . .	160—163
(6) Industries (D. & R.) Act, 1951 :	
Amendments to the Act ; Co-ordination with Drugs Act ; Definition of New Article ; Development Council for Pharmaceuticals and Drugs. . . . .	163—167
(7) Amendments to the Drugs Act . . . . .	167—172
CHAPTER VI—RESEARCH WORK : . . . .	173—183
(1) Research Work in Europe and America. . . . .	173
(2) Research Work in India :	
Research work by Government Institutions, Uni- versities, Medical Colleges and Manufacturing Con- cerns. . . . .	173—181
(3) Scope for Improvement and need for co-ordination of research work in India. . . . .	181—183
CHAPTER VII—DISTRIBUTION AND ADVERTISEMENT : . . . .	184—197
(a) DISTRIBUTION :	
(1) General . . . . .	184
(2) Methods adopted in advanced countries . . . . .	184—187
(3) Position in India and steps necessary for its improv- ment . . . . .	187—190
(b) ADVERTISEMENT :	
(1) General ; . . . . .	191
(2) Medical Representatives ; . . . . .	191—192
(3) Methods adopted in advanced countries . . . . .	192—194
(4) Advertisement of unethical products . . . . .	194—197
CHAPTER VIII—MEDICAL PROFESSION AND THE PHARMACEUTICAL INDUSTRY : . . . .	198—206
(1) General ; . . . . .	198
(2) Supply of drugs and pharmaceuticals to the medical pro- fession ; . . . . .	198—199
(3) Questionnaire for the Medical Profession ; . . . . .	199
(4) Co-operation of the Medical Profession ; . . . . .	199—200
(5) Use of compounded preparations in modern medical prac- tice ; . . . . .	200—205
(6) Medical practitioners and dispensaries ; . . . . .	205—206
(7) Labels. . . . .	206

	PAGES
CHAPTER IX— <u>TECHNICAL TRAINING FOR THE PROFESSION OF PHARMACY :</u>	207—213
(1) Status of the Profession ; . . . . .	207
(2) Drug Enquiry Committee and Bhore Committee ; . . . . .	208
(3) Pharmacy Act ; . . . . .	208—209
(4) Pharmacy Council of India ; . . . . .	209—210
(5) Degree Courses in Pharmacy ; . . . . .	210
(6) Improvement of Pharmacy in India. . . . .	211—213
SUMMARY OF RECOMMENDATIONS	214—249
CONCLUSIONS AND ACKNOWLEDGEMENTS	250—25



सत्यमेव जयते

**APPENDICES**

No.	Description	Pages
1	The Record of speeches delivered by the Hon'ble Minister for Commerce & Industry and the Hon'ble Minister for Health at the Inaugural Meeting held in Delhi on the 12th March, 1953 . . .	255—262
2-A	The dates and places of the meetings of the Pharmaceutical Enquiry Committee . . . . .	263
2-B	The names of the manufacturing concerns, research and testing laboratories and other institutions visited by the Committee . . .	264—268
3	The names of the Associations and other bodies interviewed by the Committee . . . . .	269—270
4-A	Questionnaire for Industry and Trade . . . . .	271—277
4-B	Questionnaire for Members of the Medical Profession, Public Health Authorities etc. . . . .	278—280
4-C	Questionnaire for the Wholesale and Retail Trade. . . . .	281
5-A	List illustrating the names of organic and inorganic chemicals which are required by the Pharmaceutical Industry; but the production of which the Industry need not take up . . . . .	282—283
5-B	List illustrating the names of fine chemicals and drugs, which the Pharmaceutical Industry should make an effort to manufacture. . .	284—285
6	The British Pharmacopoeial Drug Plants and their Substitutes growing in India . . . . .	286—311
7	Summary of the Recommendations of the Report of the Expert Committee (Excise) . . . . .	312—315
8	Flow-sheets for the manufacture of some essential chemicals . . .	316—350
9	Summary of the Recommendations of the Report of the Committee for the improvement of Slaughter Houses in the State of Bombay (Masani Committee) . . . . .	351—357
10	Tentative List of essential drugs, insecticides, antiseptics, disinfectants and medicinal foods, whose production in the country should be encouraged . . . . .	358—363
11	The proposed new set up of the Drugs Control Administration (centralised) . . . . .	364
12 A&B	Notes on Researches carried out under the auspices of the Council of Scientific and Industrial Research and the Indian Council of Medical Research . . . . .	365—386
13	List of Principals, Professors of Surgery, Pharmacology etc. of various medical colleges and officials of Public Health Departments of State Governments from whom replies to the Questionnaire were received . . . . .	387—394
14	List of Minimum Equipment and Reference Books for the efficient running of a pharmacy . . . . .	395—397
	<b>BIBLIOGRAPHY . . . . .</b>	389—402

## LIST OF TABLES

Table No.	Description	Pages
1	The number of questionnaires issued to the Industry and Trade	7
2	The number of questionnaires issued to the Medical Profession	8
3	The location and number of the large and small scale pharmaceutical manufacturing concerns in India . . . . .	19
4	The capital invested, labour employed, value of raw materials consumed, and sale value of finished products in Government factories, Large Scale Private Enterprise under foreign control and/or collaboration, Large Scale Private Enterprise under Indian management and Small Scale Private Enterprise . . . . .	21
5	The capital invested, value of raw materials consumed, total sales, labour employed etc. in major Central and State Governments factories. . . . .	23—24
6	The areas under poppy cultivation in different States . . . . .	30
7	Production and export of opium during 1950-51 to 1952-53 . . . . .	31
8	The quantity of opium sold to each of the State Governments for sale for oral consumption during 1953-54 . . . . .	32
9	Quantities of opium Alkaloids and their salts sold in India by the Alkaloid Factory Ghazipur and exported . . . . .	35
10	The areas under cinchona cultivation in 1939 and 1952 . . . . .	39
11	The quantities of chemicals required for extraction of quinine from cinchona bark at the Naduvattam Factory . . . . .	41
12	The quantities of different products obtained at the quinine factory Naduvattam and their sale values during 1950-51 to 1952-53 . . . . .	41
13	The quantities of chemicals required for extraction of quinine from cinchona bark at the Mungpoo Factory . . . . .	45
14	The quantities of different products obtained at the Mungpoo Factory and their sale values during 1950-51 to 1952-53 . . . . .	46
15	The imports of quinine during different months for the years 1951-53 . . . . .	49
16	The quantities and sale values of the various products made at the Bombay Government Shark Liver Oil Factory, Bombay . . . . .	52
17	The production of different grades of Shark Liver Oil and the raw materials consumed at the Kozhikode Factory . . . . .	54
18	The capacity and production in 1952 of Vaccines, Sera and Antitoxins in Government Institutions in India . . . . .	56—57
19	The production of Sulphathiazole during 1948 to 1953 at the Haffkine Institute, Bombay . . . . .	60
20	The capital investment, sale value of finished products, value of raw materials consumed, labour employed and nature of products made by the firms under foreign control . . . . .	62
21	The names of manufacturing firms in India which have entered into agreements with foreign firms and products made under these agreements . . . . .	66—68

Table No.	Description	Pages
22	The capital invested, labour employed, value of raw materials consumed, sale value of finished products etc. of the Indian managed large scale private enterprise registered under the Industries (D&R) Act. 1951 . . . . .	73
23	The capital invested, labour employed, annual sales etc. of small scale pharmaceutical establishments (excluding 18 small scale establishments under Government management or foreign control) . . . . .	78—79
24	The State-wise production and industrial consumption of alcohol in India in 1951 . . . . .	92—93
25	The capacity for carbonising coal and recovery of coaltar and quantities of coal actually carbonised and coaltar recovered in 1952 and 1953 . . . . .	100
26	The capacity of rectification units and quantities of benzene, toluene and solvent naphtha recovered in 1952 and 1953 . . . . .	100
27	The capacity of coaltar distillers and quantities of coaltar treated in 1952 and 1953 and products recovered . . . . .	100
28	The estimates of annual demand of essential drugs worked out in the flow-sheets given in Appendix No. 8 . . . . .	102—103
29	The total requirements of basic raw materials for the production of essential chemicals listed in Table No. 28 . . . . .	104—105
30	The number of slaughter houses in the different States and different types of animals slaughtered per day . . . . .	107
31	The number of glass factories Statewise with their installed capacity and production in 1952 . . . . .	108—109
32	Import of cork into India during 1948—53 . . . . .	114
33	The imports, production, installed capacity, annual demand etc. of essential drugs . . . . .	125—130
34	Government Analysts and Laboratories nominated by each State along with the number of Inspectors appointed by them for purposes of Drug Control . . . . .	155—158
35	The groupings of pharmaceutical products according to which the firms should be licenced to manufacture drugs under the Industries (Development & Regulation) Act, 1951 . . . . .	165—167



## ERRATA

- Page (ii) of Table of Contents—Under Chapter III and against Serial No. (3) for the word "Alchoh", read "Alcohol".
- Page (iv) of Table of Contents—Against 'CONCLUSIONS AND ACKNOWLEDGEMENTS', for "250 25" read "250-251".
- Page (v)—Against 'BIBLIOGRAPHY' for "389—402" read "398—402".
- Page 2—In Col. 3 against Serial No. 8 for "br" read "Member".
- Page 21—In the heading of Col. 3, for the words "out of Col. 3" read "out of Col. 2".
- Page 35—In the second line of the heading of Table No. 9, for the word "Indian" read "India".
- Page 44—For the word "shoud" appearing in line 9, read "should".
- Page 46—In the Remarks column against Serial No. (5) for the figure "1034" read "1934".
- Page 57—In the total of Col. 7, for "5,32,87,200" read "5,32,86,900" and for "(3,97,04,700)" read "(3,97,04,900)" and for "(2,64,500)cc" read "(2,64,200)cc".
- Page 57—In the total of Col. 8, for "(1,37,430)" read "(1,37,400)".
- Page 57—In the total of Col. 9, for "(8,46,280)" read "(8,46,300)".
- Page 59—In paragraph 8.6.1., for the word "whil" appearing in line 7 read "while".
- Page 63—In line 37 insert the words "carry out only processing" between the words "which" and "work".
- Page 100—In the second line of the heading of Table No. 25, for the word "ACTUALLY" read "ACTUALLY".
- Page 125—In the last line of Col. 1, under the heading "SULPHA DRUGS" for the word "dulphailamide" read "Sulphanilamide".
- Page 127—In Col. 1 under 'ENDOCRINES' delete comma between the words "Insulin" and "Lente".
- Page 127—In Col. 1 against Serial No. 7, for the word "ANTICAOGULANTS" read "ANTICOAGULANTS".
- Page 165—Against Serial No. 6(A), delete comma between the words "metal" and "compounds".
- Page 170—In the statement giving the scale of fee for general wholesalers, for the figure '55,000' appearing in line 1 under the heading 'cities with a population of', read '5,000'.
- Page 189—For the word "havs" appearing in line 28, read "have".
- Page 193—For the word "manufactures" appearing in line 3 of para. 3.3., read "manufacturers".
- Page 219—For the word "cep" appearing in 1st line, read "keep".
- Page 221—For the word "intermediaries" appearing in line 2 of recommendation 46(i) read "intermediates".
- Page 236—For the word "field" appearing in line 3 of recommendation 135, read "fild".
- Page 270—In line 36 of Col. 3, for the word "nager" read "Manager".

## CHAPTER I

### INTRODUCTION

#### 1. Appointment of the Committee.

1.1. In accordance with the Resolution No. CI-1(12)/52 dated the 14th February 1953, the Pharmaceutical Enquiry Committee was constituted by the Government of India in the Ministry of Commerce and Industry with the following as members:—

- |                                   |   |                          |
|-----------------------------------|---|--------------------------|
| 1. Major-General<br>S. L. Bhatia. | Inspector General of Medical & Health<br>Services and Secretary, Medical<br>Department, Hyderabad Government. | Chairman.<br>(Full-time) |
| 2. Dr. K. Vasudeva Rao            | Retired Director of Medical Services,<br>Madras.  | Member.                  |
| 3. Dr. B. B. Yodh .               | Professor of Medicine, Grant Medical<br>College, Bombay.  | Member.                  |
| 4. Dr. J. C. Ghosh .              | Director, Indian Institute of Technology,<br>Kharagpur.   | Member.                  |
| 5. Dr. A. K. Sen .                | 45, Ballygunj Place, Calcutta.  | Member.                  |
| 6. Dr. R. C. Shah .               | Assistant Director, National Chemical<br>Laboratory, Poona.   | Member.                  |
| 7. Dr. T. R. Seshadri             | Professor, and Head of Department of<br>Chemistry, University of Delhi, Delhi.                                | Member.                  |
| 8. Dr. H. R. Nanji .              | Managing Director, Italab Ltd., Bombay.   | Member.                  |
| 9. Sri K. R. Chandran             | Messrs. Bliss and Cotton, New Delhi.  | Member.                  |
| 10. Sri P. M. Nabar .             | Drugs Controller (India) Ministry of<br>Health.   | Member.                  |
| 11. Dr. A. Nagaraja<br>Rao.       | Industrial Adviser, Ministry of Commerce<br>and Industry.   | Member.                  |

1.2. After the sad demise of Dr. A. K. Sen in Calcutta, soon after the first meeting of the Committee, Dr. T. N. Banerji was appointed as a Member of the Committee in his place in accordance with the Notification No. Ind.(A)-1(26)/53 dated the 15th September, 1953.

1.3. Shri K. Vyasulu, Assistant Chief, Industries Division, Planning Commission worked as a part-time Secretary of the Committee till 29th June, 1953 when he was succeeded by Dr. B. Shah, who was appointed as a full-time Secretary of the Committee from that date, in accordance with the Notification No. Ind.(A)-1(26)/53 dated the 18th July 1953.

1.4. The Committee finally consisted of the following personnel:—

1. Major-General S.L. Bhatia.	Inspector General of Medical & Health Services and Secretary, Medical Department, Hyderabad Government.	Chairman (Full-time)
2. Dr. K. Vasudeva Rao	Retired Director of Medical Services, Madras.	Member
3. Dr. B. B. Yodh	Professor of Medicine, Grant Medical College, Bombay.	Member
4. Dr. J. C. Ghosh	Director, Indian Institute of Technology, Kharagpur. (Now Vice-Chancellor, Calcutta University).	Member
5. Dr. T. N. Banerji	Retired Principal, Medical College, Patna.	Member
6. Dr. R. C. Shah	Assistant Director, National Chemical Laboratory, Poona.	Member
7. Dr. T. R. Seshadri	Professor and Head of Department of Chemistry, University of Delhi, Delhi.	Member
8. Dr. H. R. Nanji	Managing Director, Italgas Ltd., Bombay.	Member
9. Sri K. R. Chandran	Messrs. Bliss and Cotton, New Delhi.	Member
10. Shri P. M. Nabar	Drugs Controller (India), Ministry of Health.	Member
11. Dr. A. Nagaraja Rao.	Industrial Adviser, Ministry of Commerce and Industry.	Member
12. Dr. B. Shah	Assistant Salt Commissioner, Ministry of Production, New Delhi.	Secretary (Full-time)

## 2. Terms of Reference.

2.1. The Committee was set up to make a comprehensive enquiry into the working of the Pharmaceutical Industry as a preliminary to considering what steps the Government should take to establish it on sound lines. The Government have mentioned in their Resolution that this industry, which in its more modern form, is of relatively recent growth and has had an uneven development so far, should be put on a sound basis in the interest of the country's health and economy.

The Terms of Reference are—

- (i) To study the working of the existing pharmaceutical manufacturing concerns in India with particular reference to:—
  - (a) the demand for the drugs produced and their essentiality;
  - (b) the quality of the drugs;
  - (c) the cost of production;
  - (d) the efficiency of the process employed; and

- (e) whether the product is made from imported intermediates and penultimate products or from basic raw materials and chemicals.
- (ii) To study the operations of foreign and/or Indian concerns, who import drugs and pack them in the country. The extent of tie-up between the wholly or partly owned Indian concerns with foreign companies;
- (iii) To recommend steps for encouraging the manufacture of important drugs, which are imported into the country;
- (iv) To enquire into the scheme of distribution of pharmaceutical products, whether imported or manufactured or packed in the country, the profit margins to Trade or Industry and the part played in this by purely Indian as well as other concerns;
- (v) All ancillary matters connected with the above.

### 3. Previous Enquiries.

3.1. *Drugs Enquiry Committee*.—In 1927, a Resolution was adopted by the Council of States recommending to the Governor-General in Council to urge all Provincial Governments to take immediate measures to control the indiscriminate use of medical drugs, and to legislate for the standardization of the preparations and for the sale of such drugs.

3.1.1. In August 1930, in response to public opinion on the subject and in pursuance of the Resolution of 1927, the Government of India appointed a Committee, known as the Drugs Enquiry Committee, with Col. R. N. Chopra as its Chairman to enquire the extent to which drugs of impure quality or defective strength were being imported, manufactured or sold in India and to recommend steps for controlling such imports, manufacture and sale in the public interest.

3.1.2. The Committee recommended: (i) Central Legislation to control drugs and pharmacy; (ii) setting up of test laboratories in all States to control the quality of production of drugs and pharmaceuticals, and a Central Laboratory to control the quality of imported drugs and also to act as an expert referee in respect of disputed analysis of samples sent by Local Governments; (iii) appointment of an Advisory Board to advise Government in making Rules to carry out the objects of the Act; (iv) setting up of courses for training in pharmacy and prescribing minimum qualifications for registration as a pharmacist; and (v) registration of every patent and proprietary medicine of undisclosed formula manufactured in India or imported from outside the country.

3.1.3. As a result of this Report, the Government of India passed the Drugs Act in 1940 to regulate the manufacture, distribution, import and sale of drugs. Drugs Rules were also framed in 1945 to serve the purposes of this Act. The Drugs Act and Drugs Rules came into force in all the Part A and Part C States in 1947. The Act and Rules have been made applicable recently to Part B States also.

3.1.4. The Central Government has also passed a Pharmacy Act in 1948 to regulate the profession of pharmacy. Under this Act, the First Registers of pharmacists have been completed by the State Governments. The minimum educational and other qualifications necessary for a pharmacist to be registered have been drawn up.

3.1.5. By the enforcement of these Acts, the State Governments have been given the responsibility of controlling the manufacture of drugs and pharmaceuticals and their sale through qualified personnel; while the Central Government controls the quality of drugs and pharmaceuticals imported into the country.

3.2. *Panel on Fine Chemicals, Drugs and Pharmaceuticals.*—Immediately after World War II, a Panel was formed by the Government of India under the late Department of Planning and Development on the lines of similar Panels for other industries, to consider and make recommendations regarding the development of fine chemicals, drugs and pharmaceutical industries with Col. R. N. Chopra as its Chairman. The Panel recommended: (i) targets of production of different drugs and pharmaceuticals to be achieved in the next 5 years and stages by which the industry was to be developed; (ii) the steps necessary for improving the supply of raw materials, required by the industry; (iii) the initiative in the manufacture of vitally important drugs such as penicillin, streptomycin, antimalarials, sulpha drugs etc. to be taken by Government; (iv) the State aid required to help the industry especially in the setting up of pilot plants for the manufacture of new products; and (v) the steps necessary for the training of technical personnel to man the industry.

3.3. *The Panel for Pharmaceutical Industry.*—A Panel for the Pharmaceutical Industry was set up in 1951 by the Central Government in pursuance of the recommendations made by the Development Committee for Industries at its meeting in December 1950, along with five other Industrial Panels on other important industries. The Panel was to review the industry in the light of the changed conditions brought about by partition, the commencement of the Korean War and other factors, and to report, *inter-alia* on the requirements of raw materials of the Industry, the ways in which productive capacity could be increased within a short period, and to suggest measures for the establishment of new capacity where it was considered necessary. The Panel furnished in their report, a list of raw materials giving the quantities required and their sources. For securing increased production, they recommended a change in the import policy of Government. For the establishment of new capacity, they considered that the schemes of some of the firms for the manufacture of citric acid, phenobarbitone (B.P.), nikethamide and Para-amino-Salicylic acid (P.A.S.) etc., should be given assistance.

3.4. *Planning Commission.*—The Planning Commission which also examined the Industry have in addition to the recommendations for the development of the chemical industry in general, made the following recommendations concerning the pharmaceutical industry in particular:—

- (i) "Efforts should be made by all the existing manufacturers and newcomers to manufacture as many pharmaceutical chemicals and drugs as possible using basic chemicals

and/or simple intermediates which may either be imported or produced locally according to circumstances. Whenever penultimate products and complex intermediates are used in the first instance to start the industry, efforts should be directed towards manufacturing such products within the country as soon as possible;"

- (ii) "Higher priority should be given to the manufacture of synthetic drugs than to the conversion of imported drugs into tablets or finished preparations for use, since capacity for the latter, even when it becomes inadequate, could be easily arranged."
- (iii) "It is necessary, particularly in the pharmaceutical industry, to put emphasis on quality rather than on volume of production. Standardisation of products and distribution of only ethical goods should be enforced as far as possible."
- (iv) "Considering that the products of the drugs and pharmaceutical industry are essential for the well-being of the nation and for alleviating human suffering, steps should be taken to bring down the cost of such materials as much as possible. The recent tendency prevalent among some manufacturers to undertake development by associating a number of related companies together which only tends to increase the cost of the products, should be discouraged."
- (v) "Although the production of shark liver oil is being carried out under the auspices of some Government Departments and also by some private agencies, the fishing of shark and extraction of oil have not developed on proper lines. The Fisheries Departments of different maritime States should co-operate with each other and co-ordinate their activities. Refrigeration facilities are also necessary at important centres of fishing;

On account of the bad odour and taste of shark liver oil, it is sometimes not acceptable to certain sections of the people. The vitamin content of the oil free from disagreeable odours could, however, be prepared in a concentrated form by molecular distillation. Units for deodorising and improving the taste of the oil should be established in important centres of production. The encapsulating of such shark liver oil in gelatin capsules will also mitigate to a large extent the bad odour and taste of the oil;"

- (vi) "Standards for drugs and chemicals.—At present, there is no arrangement for the collection of animal tissues and glands under hygienic conditions for the production of biological products. The Ministry of Commerce and Industry is understood to have taken up the question of arranging cold storage facilities in slaughter houses with the State Governments. Early steps have to be taken

to provide these facilities at least at some of the big cities."

#### 4. Present Enquiry:

4.1. The Committee was set up on the 14th of February, 1953 and its inaugural meeting held in Delhi on the 12th March, 1953. The record of speeches delivered by the Hon'ble Minister for Commerce and Industry and the Hon'ble Minister for Health, Government of India are given in Appendix No. 1. The Committee started work from the 7th of May 1953 when its second meeting was held in Bombay. During its stay in Bombay, the Committee also visited several manufacturing firms and held discussions with the local Associations and the State Government. The work of the Committee was commenced in right earnest after the Chairman, Major-General S. L. Bhatia, was able to relinquish his post in Hyderabad and move to Delhi in June 1953, when a full-time Secretary was appointed and an office for the Committee was set up. The Committee thereafter undertook a series of tours and visited the important manufacturing centres in the country viz., the States of Bombay, Bengal, Madras, Mysore, Punjab, Uttar Pradesh, Hyderabad, Travancore-Cochin and Assam and held nine meetings. The dates and places of the meetings and the manufacturing concerns, research and testing laboratories and other institutions visited by the Committee are given in Appendix No. 2A and B. Besides, a survey of the small scale manufacturers in Bombay, Madras, Calcutta and Delhi was also made by four Sub-Committees formed out of the members of the Committee and the concerned State Drugs Controllers who were co-opted as members for this purpose. During the Committee's visits to the different centres of production, they met the Ministers and officials of State Governments, and the various associations of manufacturers, traders, and medical men and discussed with them the diverse problems of the industry. A list of associations and other bodies interviewed by the Committee is given in Appendix No. 3.

4.2. In order to collect full and upto date information on the industry, the Committee issued three detailed questionnaires (i) for the Industry and Trade; (ii) for the Medical Profession; and (iii) for the Whole Sale and Retail Trade. These questionnaires are given in Appendix No. 4-A, B and C.

4.2.1. *Questionnaire for the Industry and Trade.*—The questionnaire for the Industry and Trade was issued to manufacturers of drugs licensed by the State Governments, importers of pharmaceuticals, their respective associations and all State Governments. The response from the manufacturers was very poor and on further scrutiny, it was found that a number of manufacturing establishments licensed by the State Governments to whom the questionnaire had been issued had either closed down or were mere dispensing houses and did very little manufacturing work. Therefore, a revised list of manufacturers was prepared and the matter was pursued again to obtain their replies. The revised list included all the manufacturers who were registered under the Industries (Development and Regulation) Act, 1951. The following table shows the number of firms, licensed by the State Governments to manufacture drugs and pharmaceuticals and licensed by the Central Government under the Industries (Development and Regulation) Act. It also shows the number of firms with whom the replies to the questionnaire were followed up.

TABLE NO. 1—THE NUMBER OF QUESTIONNAIRES ISSUED TO THE INDUSTRY AND TRADE

State	No. of firms licensed by the State Government to manufacture drugs and pharmaceuticals	No. of firms licensed by the Central Government under the Industries (D. & R.) Act, 1951	No. of firms with whom the reply to the questionnaire was followed up
<hr/>			
<b>PART 'A' STATES :</b>	<b>1543</b>	<b>72</b>	<b>152</b>
Assam . . . . .	11	..	4
Bihar . . . . .	16	1	4
Bombay . . . . .	591	35	64
Madhya Pradesh . . . . .	39	..	..
Madras . . . . .	135	5	13
Orissa . . . . .	1	..	..
Punjab . . . . .	40	3	7
Uttar Pradesh . . . . .	146	3	10
West Bengal . . . . .	564	25	50
<hr/>			
<b>PART 'B' STATES :</b>	<b>34</b>	<b>3</b>	<b>12</b>
Hyderabad . . . . .	6	2	6
Madhya Bharat . . . . .	3	..	..
Mysore . . . . .	10	1	2
Saurashtra . . . . .	9	..	1
Travancore Cochin . . . . .	6	..	3
<hr/>			
<b>PART 'C' STATES :</b>	<b>64</b>	<b>..</b>	<b>9</b>
Ajmer . . . . .	3	..	..
Bhopal . . . . .	3	..	..
Delhi . . . . .	56	..	9
Kutch . . . . .	2	..	..
<hr/>			
<b>OTHER STATES :</b>	<b>2</b>	<b>..</b>	<b>2</b>
Jammu & Kashmir . . . . .	2	..	2
Total . . . . .	1643	75	175

4.2.2. *Questionnaire for the Medical Profession.*—The following table shows the number of questionnaires issued to medical colleges,



public health and medical authorities and medical associations and the number of replies received:

TABLE NO. 2—THE NUMBER OF QUESTIONNAIRES ISSUED TO THE MEDICAL PROFESSION

To whom issued	No. of questionnaires issued	No. of replies received
1. Medical Colleges . . . . .	33	28
2. State Public Health and Medical Authorities . . . . .	35	25
3. Medical Associations . . . . .	2	2
TOTAL . . . . .	70	55

The response has been satisfactory.

4.2.3. *Questionnaire for the Wholesale and Retail Trade.*—The questionnaire for the Wholesale and Retail Trade was supplied to the concerned associations during the Committee's meetings with them and they were requested to obtain replies from their members and consolidate them before forwarding to the Committee. The following are the names of the associations to whom the questionnaire was distributed:—

1. All-India Chemists and Druggists Federation, Lucknow.
2. Delhi State Chemists Association, Delhi.
3. Chemists and Druggists Association, Bombay.
4. Chemists and Druggists Association, Bangalore.
5. Chemists and Druggists Association, Madras.
6. Chemists and Druggists Association, Baroda.
7. Chemists and Druggists Association, Amritsar.
8. Chemists and Druggists Association, Calcutta.
9. Chemists and Druggists Association, Hyderabad.
10. Retail and Dispensing Chemists Association, Bombay.
11. Chemists and Druggists Association, Bareilly.
12. Gujrat Chemists Mahamandal, Ahmedabad.

The All-India Chemists and Druggists Federation, to which most of the associations are affiliated as well as a few of the individual associations and their members have sent their replies.

4.3. In addition, the various associations with which the Committee held discussions have submitted memoranda on the Terms of Reference of the Committee. A considerable amount of useful information has been gathered from the replies to the questionnaires, visits to factories, memoranda submitted by the Associations and during discussions with the various associations, State Governments and other bodies.

4.4. All these unfortunately tend to show that the position in regard to production of pharmaceuticals and drugs in the country is still in no way inspiring. The import of drugs and medicines has been increasing rapidly as will be seen from the following statement:—

Year	Value of drugs and medicines imported (in rupees)
1949-50 . . . . .	7,85,96,000
1950-51 . . . . .	10,51,50,708
1951-52 . . . . .	15,60,38,109

Out of these nearly 80 per cent. consisted of antibiotics, sulpha drugs, vitamins, hormones and other chemotherapeutic products. The springing up of a large number of firms both Indian and foreign for mere processing of imported products with little or no programme for undertaking their production from basic chemicals has been tending to perpetuate the dependence of this country on foreign imports for these vital products. Some of the manufacturers are linking themselves with foreign firms mostly for marketing their products, using their trademarks, processing of unessential items etc., and thereby increasing the ultimate cost of the product to the consumer, and causing sometimes wastage of foreign exchange. They are not also in many cases taking full advantage of such foreign participation, as in the direction of establishment of production of basic chemicals, achieving high standards of quality of the products etc. Some of the enterprises undertaken both by the Central and State Governments do not appear to be functioning on right lines due to certain inherent defects in their composition, organisation and working. The import of basic chemicals and intermediates required by the existing pharmaceutical industry has also been increasing from year to year. Considerable difficulty is being experienced by the manufacturers in obtaining raw materials of the desired quality and quantity in cases like vegetable drugs, endocrine glands and tissues owing to their collection and marketing not being properly organised.

4.4.1. The introduction of Drugs Act and Rules thereunder has not brought about the desired results in improving the quality of products manufactured and/or offered for sale in the country. The menace of manufacture and sale of spurious and sub-standard drugs still continues. Through advertisement in the press and propaganda, tall claims are being made for useless preparations and the gullible public are being exploited.

4.4.2. The promulgation of the Industries (Development and Regulation) Act enforcing control on the pharmaceutical industry has brought with it several problems concerning its application, the future organisation necessary for controlling the industry, and other aspects on which the Union Government would like the Committee to offer their recommendations.

4.5. The Committee cannot emphasise too strongly the importance of achieving self-sufficiency in the supply of such vital products like pharmaceuticals and drugs and maintenance of a high standard of their quality. Some years ago, the pharmaceutical industry was mainly called upon to produce substances of vegetable and animal origin or of a simple inorganic nature. Today, it has to deal with the production of complex organic chemicals, mostly synthetic, and of specific value in the treatment of acute infections, nutritional deficiencies and metabolic disorders, endocrine dysfunctions etc. The manufacture of these products needs considerable technical knowledge, special plant and equipment, perfect laboratory control and facilities for research to keep pace with the rapid developments in the field of medicine. The future of the industry would, have, therefore, to depend on organisations which can provide these facilities and produce such drugs starting from basic chemicals within the country itself.

## 5. Report:

5.1. In the preparation of this Report, the Committee have kept in view the need for giving a comprehensive idea of the conditions prevailing in the different sections of the industry and to suggest methods by which they could co-ordinate their activities and put the industry on a sound footing and eliminate the manufacture and sale of products of sub-standard quality and spurious nature. The Report begins with a general discussion on the scope of the industry in India in relation to the existing conditions and in comparison with the development and scope of the industry in some of the advanced countries. An account of the availability of basic raw materials of the industry and need for improving its supply has been given. The demand for essential drugs and steps necessary for establishing their production in the country have been discussed. To improve control on quality and help the industry to develop on right lines, measures including those required to bring about a more effective operation of the Drugs Act and the Industries (Development and Regulation) Act have also been discussed. The importance of research for the development of the industry and the need for increasing the existing research activities and bring about a better co-ordination in the work that is being carried out at present by different organisations has been examined. The Report also deals with the problems concerning distribution and advertisement of pharmaceutical products, the profession of pharmacy, the need for improving its status and providing more facilities for training of pharmacists. The importance of closer co-operation between the medical profession and the pharmaceutical industry for its development has been emphasised. At the end of the Report, a summary of the recommendations has been incorporated. In the Report, certain repetitions of facts and conclusions derived from them may be noticed, but these have been advisedly allowed to remain for a clearer appreciation of the problems discussed.

## CHAPTER II

### PHARMACEUTICAL INDUSTRY—ITS SCOPE & DEVELOPMENT

#### (a) ITS SCOPE AS UNDERSTOOD IN OTHER COUNTRIES AND IN INDIA

##### 1. Early History:

1.1. The use of simple vegetable remedies for curing ailments was perhaps one of the earliest efforts of man. The application of a leaf as a wound dressing was probably the very first of such practices. The main drugs of antiquity have all been of vegetable and animal origin. The useful plants were collected by herb gatherers who practised a complex ritual in their search. When employed alone, they were known as 'simples' but were termed 'compounded' when used mixed with one another. The usage of these terminologies still persists.

1.2. There are records of the use of herbal medicines from the days of the ancient Egyptians. Hippocrates in the 4th Century B.C., taught the value of plants for treating human ills in ancient Greece. Out of the 400 herbs employed by him, nearly half of them are reported to be still in use today. The earliest publication on the herbals dates back to 300 B.C., when Theophrastus, a pupil of Aristotle wrote his 'Historia Plantarum'. The first 'Materia Medica' was written in A.D. 60 by Dioscorides, a Greek Surgeon in the army of Nero.

1.2.1. During the time of Galen, the Greek Physician who practised in Rome in A.D. 200, a large variety of herbs were in use. He classified them and developed the art of extracting their essential principles. The products derived from such herbs are, therefore, even today known as 'Galenicals'.

1.2.2. After the end of the Graeco-Roman power, the physicians of the East made notable contributions to 'Materia Medica' and added numerous remedies to the list. They discovered processes like distillation, sublimation etc., which have rendered great service to the advancement of this branch of science.

1.2.3. In the 15th and 16th Centuries, as a result of belief in alchemy, occultism and mock magic of every sort, medicine became entangled with these dubious practices. Vast numbers of the drugs which came into use during this period are known to be useless. They were mixed up with magic or superstitious beliefs especially the animal remedies such as 'eye of newt and toe of frog'. Strange theories not based on scientific foundations had taken root and were being used to determine the choice of a remedy, like the 'doctrine of signatures', according to which leaves which were shaped like the human ear, were used for ear-diseases, like the lungs for lung diseases and so on.

## 2. The Pharmaceutical Industry at present:

2.1. The origin of the present-day pharmaceutical industry dates back to the early 19th Century, when the earliest pharmacopoeias were published by the Royal College of Physicians, in London, Edinburgh and Dublin in 1837 and the first British Pharmacopoeia, which replaced these Provincial Pharmacopoeias, was published in 1864. These early editions of the Pharmacopoeias were divided into two sections: (i) "Materia Medica" devoted to drugs of vegetable and animal origin and (ii) "Preparations and Compounds" Section in which methods for the manufacture of the various preparations were described. During these early days of the industry, the manufacture of pharmaceutical chemicals was intended largely to be carried out in the small scale laboratories of the retail pharmacists. This practice continues even today to some extent. The early B. P. monographs indicate the small scale of manufacture undertaken and the primitive apparatus and plant used for the purpose.

2.2. Within the last decade entirely new groups of pharmaceutical chemicals have come into increasing use. With the rapid advance in the treatment of diseases, the demands on the pharmaceutical industry both in its production technique and its research development have become heavier and more exacting. Reaction vessels, pipelines and general equipment are now necessary to be made from a variety of material supplied by the Metal, Rubber and Plastics Industries. Preparation of pharmaceuticals has passed from the retail pharmacists to the pharmaceutical manufacturer. The old conception that the scope of the industry was necessarily restricted to making only the drugs available in a dosage form has undergone radical change. Many pharmaceutical establishments, which started work as retail pharmacists, have moved with the times, and adapted themselves to the changing conditions, some of them being the foremost manufacturers of fine chemicals, synthetic drugs and antibiotics in the world today. In this connection, the following extract from an Article entitled "Pharmaceutical classifications" appearing in the Journal of Drugs and Cosmetic Industry of September 1953 would be of interest.

"But a basic change has taken place in the ethical or pharmaceutical drug manufacturing industry itself. Years ago these houses were, almost exclusively, formulators. That is, they bought their raw materials from chemical manufacturers, botanical drug houses and other suppliers, and then they formulated their products. Their manufacturing operations, for the most part, were limited to the making of pills and tablets, capsulating, extraction of botanical drugs, manufacture of simple things such as milk of magnesia, ointments and so forth. In other words, these manufacturers were largely houses, who prepared known drugs in what are called "dosage forms". New discoveries were few and far between, so that the main function of these manufacturers was to supply the pharmacist and the doctor with preparations, which were formulated very carefully in large volume, thus cutting down the time which the pharmacist spent in this sort of work.

But today, the picture is quite different. Due to the great acceleration in the tempo of pharmaceutical discoveries, the outstanding

pharmaceutical manufacturers have become basic producers of the new products, which they have discovered or which they have decided they should be marketing. Thus, these pharmaceutical houses are, in fact, chemical manufacturers, in many cases producing by various means, some of the most complicated organic chemicals, that have ever been produced. Some years back, a pharmaceutical manufacturer who discovered some new product of this sort, contracted with a chemical manufacturer to make the desired chemical just for him. This was a sort of a private brand business in chemicals, which is still carried on for manufacturers in other industries, although not very much any more in the drug business. This has meant the erection of huge chemical manufacturing plants by the pharmaceutical manufacturers, and the engagement of personnel skilled in chemical plant operations to run them. It has also been the cause of companies, who were large suppliers of chemicals to undertake the work of drug and pharmaceutical manufacturers and of becoming marketers of finished drugs and pharmaceuticals. Thus, as the pharmaceutical manufacturers have, to a marked degree, backed into the chemical manufacturers, chemical manufacturers have in several instances, moved forward into the marketing of pharmaceutical preparations. Furthermore, the purchase of pharmaceutical manufacturing enterprises by chemical manufacturers as a means of obtaining quick and recognised distribution for their pharmaceutical chemicals has taken place in several instances, and rumours of more such mergers are always being heard. Not that this entry into the chemical manufacturing business has proved a profitable venture in all instances. Once a pharmaceutical manufacturer decides to engage in the manufacture of one of the new pharmaceutical chemicals, which is being marketed by several houses, he engages in competition in the production of the product in addition to being already in competition in the marketing of it. This was very vividly depicted in the penicillin situation, when the enormous plants of several manufacturers became obsolete within a relatively short period of time due to improvements in production methods which cut the cost of penicillin to such a point that the drug could be sold at less than the cost of production in the older plants".

2.3. But in this country a section of the industry, so far developed primarily for processing work, still contend that, its scope is confined to mere processing of bulk pharmaceuticals and of making it available in a dosage form like tablets and capsules, as proprietary preparations like elixirs and tonics, as injectables filled in ampoules or vials and so on. Many comparisons have been drawn by them to illustrate that the pharmaceutical industry is complementary to the chemical industry and the scope of the former does not include the manufacture of chemicals. In the same way as in the scope of the tailoring industry, the engineering industry, the newspaper industry and the cinematograph industry, it does not extend to the manufacture of their basic raw materials like the textiles, steel, paper and raw films respectively, they claim that the scope of the pharmaceutical industry does not include the manufacture of the fine chemicals required by it. They go even to the extent of considering it erroneous to expect the pharmaceutical industry to enlarge its activity to produce the fine chemicals or the bulk pharmaceuticals required by it

2.3.1. They maintain that the manufacture of fine chemicals and synthetic drugs in bulk comes only within the scope of the chemical industry and due to the backwardness of this branch of the industry in India, these products had to be imported to meet their requirements. Further, they appear to feel that it was only because of this state of the chemical industry of the country that the Government were bringing pressure to bear directly or indirectly on pharmaceutical firms to undertake their manufacture although a large number of them were quite incapable of doing so. The Committee are of the opinion that this is not the right outlook to be taken by the Industry. With the rapid developments in the field of pharmacology and medicine and the discovery of new therapeutic products, if the pharmaceutical industry in India did not undertake the manufacture of such synthetic drugs and fine chemicals, it would not be keeping pace with the progress of the industry in other countries and the dependence of the country on imports for such vital goods would continue. The future of the pharmaceutical industry would, therefore, have to be in the manufacture of synthetic drugs, fine chemicals and antibiotics and their final processing.

2.4. While on this point, it should also be stated that a section of the industry in the country has realised the position and has been making sincere efforts to manufacture fine chemicals and synthetic drugs. During these attempts, it has come across certain handicaps due to lack of production in the country of basic chemicals like coal-tar products, solvents etc., and these have to be set right as soon as possible. At this stage, it is sought only to remove the confusion, that appears to prevail in the minds of some of the manufacturers that the pharmaceutical industry has been called upon forcibly to produce even the basic chemicals like mineral acids, coal-tar products, solvents etc.

2.4.1. Two lists illustrating (i) the names of organic and inorganic chemicals which are required by the pharmaceutical industry but the production of which the industry need not take up, as they may be reasonably considered to fall outside its purview; and (ii) the names of fine chemicals and drugs, which the pharmaceutical industry should make an effort to manufacture for making the country less dependent on foreign imports, are attached. (Appendix No. 5-A and B.)

2.5. It is not the Committee's intention that every pharmaceutical manufacturer should undertake the manufacture of his requirements of all fine chemicals and drugs. This is neither economical nor feasible. In this country to day, in a number of units, there are already two fairly well-defined sections in operation—one section comprising of manufacturing departments producing fine chemicals and drugs, and the other for merely processing bulk pharmaceuticals either imported or locally produced into a dosage form. It is necessary to bring about a greater co-ordination between these two sections of the industry. Each manufacturing concern should endeavour to produce as many of the fine chemicals and drugs as possible starting from basic chemicals, and/or intermediates as close to the basic chemicals as practicable for the time being, in quantities sufficient to meet, not only its own requirements, but also of other firms who process them. By such co-operation between the different units and the pooling of their resources, rapid development of the pharmaceutical industry

will be ensured. Such co-operation is all the more essential, as the dye-stuff industry in this country is practically non-existent, while in other advanced countries like Germany, United Kingdom and U.S.A., this industry is well developed and supplies a large number of intermediates and fine chemicals required by the pharmaceutical industry.

2.6. While such complementary efforts require to be encouraged, there is already at present a certain amount of lack of co-operation between the two sections of the industry. Some of the processing firms prefer to import their supplies of fine chemicals or intermediates rather than purchase them from firms which have undertaken their production in the country. On the other hand, certain firms which are endeavouring to produce these fine chemicals and intermediates, do not wish to supply them to others for processing. Such non-cooperation between firms should be thoroughly discouraged and a radical change in outlook brought about for fostering a healthy development of the industry. Government should actively encourage co-ordination between the two sections of the industry and wherever required, even sponsor the manufacture of fine chemicals and drugs to bring about a co-ordinated development of the industry.

#### (b) DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY IN OTHER COUNTRIES AND IN INDIA

##### 1. Pharmaceutical Industry in the U.K.

1.1. Before World War I, the initiative in the production of chemotherapeutic substances had remained with Germany. The German Organic Chemical Industry and the Bayer-Meister Lucius concern (predecessor of the pharmaceutical branch of I.G. Farbenindustrie) were the main producers of these products and met almost the entire requirements of the world. Until the beginning of World War I, Great Britain was without any source of complex organic chemicals. The principal pharmaceutical chemicals manufactured in that country were only either, chloroform, bismuths, mercurials etc. With the outbreak of the War as Great Britain was completely cut off of its supplies from Germany, the industry made rapid strides and undertook the production of organic arsenicals, barbiturates, aspirin, phenacetin etc. Even after the war, the British manufacturers continued to expand the industry under the protection granted to them by their Government in spite of severe German competition, so that by 1939, British manufacturers were producing large quantities of sulphanilamide and other chemotherapeutic substances.

1.2. The World War II gave a further impetus to the British Pharmaceutical Industry. The extension of this war to mosquito ridden areas, and the diminution of supplies of cinchona for the manufacture of quinine with the conquest of Java led to the development and production of synthetic antimalarials like mepacrine and paludrine. The famous antibiotic penicillin also made its appearance during this period. Owing to rapid progress in the production techniques and in the quantum of production, efficiency was greatly increased and the price of the products brought down. The production of insulin, thyroxine and some of the steroid hormones secreted



by the adrenal, ovarian and testicular glands as well as their derivatives and synthetic analogues, was greatly increased. In the field of vitamins, the isolation of Vitamin 'A' concentrates from fish-liver oils by the process of molecular distillation was developed. The production of Vitamin 'B<sub>1</sub>', Vitamin 'C' and Vitamin 'D<sub>2</sub>' was undertaken on a large scale. In the field of anaesthetics and analgesics, the production of opium alkaloids, curare alkaloids and synthetic muscle relaxants like mephenesin and other synthetic products for the relief of hypertension was undertaken. After the war, production of antibiotics has been greatly increased and large quantities of these products are being exported by U.K.

## **2. Pharmaceutical Industry in the U.S.A.**

2.1. The development of medicinal chemicals in America has also passed through a similar phase of development. Before World War I, it depended almost entirely on Europe for its supplies. The manufacture of pharmaceuticals at this period was confined only to well-established products like morphine, quinine, bismuth salts, citric acid and other medicinal products. The first major factor in bringing about a change in the pattern of production was World War I. During 1914, the production of important chemicals like phenol, salicylates, barbiturates, arsenicals was developed. After the war, the tempo of development in the field of fine chemicals and pharmaceuticals was maintained by protecting the chemical industry with high tariffs on all coal-tar products. During the period 1920 to 1930, a large number of vitamins were isolated for the first time and their production on commercial scale undertaken. In 1930, the production of sulpha-drugs was established on a commercial scale. With the development of new and better testing methods for the screening of the chemicals against a variety of diseases, a host of chemotherapeutic products were developed. During World War II, and with the advent of antibiotics, a variety of this group of products was produced in large quantities and put on the market.

2.2. A well organised team of research workers in microbiology, organic chemistry and pharmacology carrying out investigations in close collaboration in well-equipped laboratories maintained by the industry and the Federal Government of the U.S.A., are bringing to light new antibiotics, hormones and vitamins. With the vast experience and resources in production technique so far developed, many new drugs are being increasingly produced. The U.S.A., today possesses approximately 70 per cent. of the world production facilities for penicillin, 80 per cent. of the production capacity for streptomycin and almost 95 per cent. of the production capacity for the wide spectrum antibiotics, chlortetra-cyclin (aureomycin), chloramphenicol, oxytetra-cyclin (terramycin), erythromycin (ilotycin) etc.

## **3. Pharmaceutical Industry in India.**

3.1. The Pharmaceutical Industry in India, when compared with the industry in U.K., and U.S.A., may be considered to be almost non-existent. The practice of modern system of medicine came into vogue in India with the advent of the British Rule. It was primarily introduced to provide medical relief to those, who came to administer

this country; but very soon the system gained popularity among the people and large numbers adopted it. Before the British regime, only the indigenous systems of medicine prevailed. The Ayurvedic system was at its zenith in the early centuries of the Christian era and in the Ayurvedic texts of these times, the various herbs known and used by the ancient Hindus have been described. Their knowledge of Materia Medica, drug therapy and toxicology, as revealed from these ancient texts, appears to have been far in advance of other countries during that period. After the successive Greek Scythian and Mohammedan invasions of India, the Ayurvedic system of medicine slowly declined. The Muslim conquerers brought with them the Arabian healing systems, which were also well-advanced for that period. The Arabian systems of medicine brought by the Muslims were based on scientific doctrines, which they had inherited from the Greeks and to which they had made their own contributions also in the domain of chemistry and Materia Medica. Between the Hindu and the Arabian systems of medicine, which have lasted many centuries in the country and which are still in vogue today, there has been a great deal of inter-mingling. It is not proposed to dilate on the value of these different indigenous systems of medicine in the country today, as any such effort would be out of the scope of the Committee. It will suffice to indicate only the retarding influence, they appear to have on the modern system of medicine. Even today, the majority of the people still adopt the indigenous systems of medicine and this accounts partly for the belated development of the pharmaceutical industry and the tendency of several manufacturers to make non-allopathic preparations in addition to the processing of drugs according to the modern system.

3.2. The Pharmaceutical Industry in India, has also had several vicissitudes, which account for its backwardness. The pioneering efforts of Acharya P. C. Ray, towards the end of the 19th Century, marked the beginning of this industry in the country, when he commenced with the manufacture of simple galenicals. His efforts to start a pharmaceutical industry were soon followed by other attempts in Western India, notable among them being by Shri T. K. Gajjar and Rajmitra B. D. Amin at Baroda. These pioneers had to work against many difficulties such as public prejudice, lack of government patronage, foreign competition etc. During the First World War, the industry received some fillip as the local demands increased several-fold and imports were almost completely cut off. The production of caffeine from tea-dust, and surgical dressings were established during this period in addition to increased manufacture of galenicals. Immediately after World War I, imports of foreign products, which had stopped completely during the war period were resumed again. Since no restrictions were imposed on their entry, competition increased and the industry again received a setback. In spite of this adverse position in 1930, the manufacture of biological products like sera and vaccines, anaesthetics like ether and chloroform, and coaltar distillation products such as naphthalene, cresol etc., was undertaken by the industry.

3.3. The outbreak of World War II gave an impetus to the industry. The manufacture of a number of alkaloids like ephedrine, santonin, strychnine, morphine, emetine, atropine and codeine was

undertaken during this period. Chemotherapeutic drugs such as arsenicals, anti-dysenteric, anti-leprotic drugs, colloidal preparations of calcium, silver, manganese, iodine etc. were made in the country. The Shark Liver Oil Industry came into existence and was able at the end of the hostilities to make supplies of shark liver oil to even some of the devastated parts of Europe for assisting in their rehabilitation. The manufacture of glandular products, such as liver extracts, pituitary extracts, adrenalin solutions was also undertaken. The country became practically self-sufficient in the production of sera and vaccines. The Indian producers, who were meeting only 13 per cent. of the medicinal requirements of the country in 1939, were in a position to meet up to 70 per cent. of the requirements of the country by 1943 in spite of the fact that the Government demand had also increased considerably during this period for meeting the requirements of the Armed Forces in the Middle and Far-East.

3.4. Even after the end of the hostilities, the world shortage of pharmaceuticals and drugs continued and the tempo of development of the pharmaceutical industry was maintained and export markets for galenicals, alkaloids etc., were developed. But this happy position did not continue for long. Competition from other countries with better established and well-known pharmaceutical producers soon replaced the Indian products from the export markets. Even within the country, the Indian industry had to face severe competition from foreign producers.

3.5. Although, the pharmaceutical industry during the war had developed to meet the major part of the country's requirements, its activities in the field of fine chemicals and synthetic drugs were mainly confined to mere processing and manufacture of compounded preparations and it did not extend rapidly to their production starting from the basic chemicals. Its development during the war years had been uneven, and dependence on foreign imports for basic drugs came into prominence. Also with the rapid development in the fields of pharmacology and medicine, a number of chemotherapeutic products and antibiotics completely replaced a large number of other drugs, which were commonly used. The Indian pharmaceutical industry could not keep pace with these rapid developments, with the result, that many of the products made by the industry became obsolete and surplus and the new drugs whose production had not been developed, had to be almost solely imported.

3.6. The great boom for pharmaceutical products during the War resulted in very many firms entering the industry for making mainly products which were in heavy demand. They are now finding it difficult to market their products. These manufacturers have abandoned even the little production of synthetic drugs, they had undertaken during and immediately after the War, as they now find it uneconomical with the existing prices in the market. They are, therefore, now mainly extracting therapeutic agents from botanical drugs, or merely mixing and blending imported bulk pharmaceuticals and producing tablets, capsules, powders and liquids of various types and of varying formulations. Although, a number of long established firms are indulging in this practice to a greater or smaller degree, the later entrants, who have not been in existence long

enough to establish a real reputation, are having a shake-down. As competition is getting keener, sub-standard preparations are being marketed. With the setting up of processing houses by foreign firms with established reputation, the position of these firms is becoming more and more difficult. Although the foreign firms carry out similar operations, they have generally better equipped establishments and keep abreast of the new trends and new discoveries in medicine with a view to issuing new or approved preparations. They have established markets for their products and have a better access to the supply of bulk pharmaceuticals, which they obtain from their principals in their own country.

(c) PRESENT POSITION OF THE INDUSTRY IN INDIA

1. Location:

1.1. The distribution of large and small scale pharmaceutical manufacturing concerns in the different States is given in the following table:

TABLE NO. 3—THE LOCATION AND NUMBER OF THE LARGE AND SMALL SCALE PHARMACEUTICAL MANUFACTURING CONCERNS IN INDIA

State	No. of large scale concerns	No. of small scale concerns
I	2	3
<b>PART 'A' STATES :</b>	<b>72</b>	<b>1,471</b>
Assam . . . . .	..	11
Bihar . . . . .	1	15
Bombay . . . . .	35	556
Madhya Pradesh . . . . .	..	39
Madras . . . . .	5	130
Orissa . . . . .	..	1
Punjab . . . . .	3	37
U.P. . . . .	3	143
West Bengal . . . . .	25	539
<b>PART 'B' STATES :</b>	<b>3</b>	<b>31</b>
Hyderabad . . . . .	2	4
Madhya Bharat . . . . .	..	3
Mysore . . . . .	1	9
Saurashtra . . . . .	..	9
Travancore-Cochin . . . . .	..	6
<b>PART 'C' STATES :</b>	<b>..</b>	<b>64</b>
Ajmer . . . . .	..	3
Bhopal . . . . .	..	3
Delhi . . . . .	..	56
Kutch . . . . .	..	2
<b>OTHER STATES :</b>		<b>2</b>
Jammu & Kashmir . . . . .	..	2
<b>TOTAL</b>	<b>75</b>	<b>1,568</b>

1.2. A large number of them are concentrated in the States of Bengal and Bombay, while in the other States, the industry is comparatively still in early stages of development. The lead taken by the States of Bengal and Bombay for the development of the industry could be partially attributed to the pioneering efforts of the founders of this industry in these States. The Pharmaceutical factories in the country can be divided into four distinct categories based on their ownership and size: (i) Government factories; (ii) Large Scale Private Enterprise under foreign control and/or collaboration; (iii) Large Scale Private Enterprise under Indian management; and (iv) Small Scale Private Enterprise.

1.2.1. The following table shows the number of factories, their capital investment, labour employed, value of raw-materials consumed and sale value of finished products, under each of these categories:



TABLE NO. 4—THE CAPITAL INVESTED, LABOUR EMPLOYED, VALUE OF RAW MATERIALS CONSUMED AND SALE VALUE OF FINISHED PRODUCTS IN FACTORIES UNDER EACH OF THE ABOVE FOUR CATEGORIES

Type of factories	Total No. of factories	No. of factories out of Col. 3 registered under the Industries (D. & R.) Act	Present capital invested	Sale value of products made in 1952	Value of raw materials consumed in 1952		Labour employed	
					Indigenous	Imported	Technical	Non-Technical
I	2	3	4	5	6	7	8	9
(i) Major Government Factories	11	7	1,48,14,900	1,16,35,200	45,74,700	14,70,000	181	1,492
(ii) Large Scale Private Enterprise under Foreign Control and/or collaboration	28	14	6,90,38,390	13,13,49,310	59,72,300	4,17,15,850	354	3,126
(iii) Large Scale Private Enterprise under Indian Management	54*	54*	9,25,86,050	13,38,29,473	1,73,05,882	2,23,54,850	1,076	15,896
(iv) Small Scale Private Enterprise	1,550	..	6,00,00,000	7,00,00,000	2,50,00,000	70,00,000	1,700	8,300
TOTAL	1,643	75	23,64,39,340	34,68,13,983	5,28,52,882	7,25,40,700	3,311	28,814

\*Includes four factories with foreign collaboration.

## (i) GOVERNMENT FACTORIES

**1. General:**

1.1. Both Central and State Governments have set up factories and participated in this industry. Among the Central Government factories are the Medical Stores Depots at Bombay and Madras, the Opium Factory at Ghazipur, the contemplated Penicillin factory at Pimpri and the D.D.T. factory at Delhi. Among those of the State Governments are the Quinine Factories at Naduvattam and Anamalai run by the Madras Government, the Quinine Factory at Mungpoo run by the Bengal Government, and the Shark Liver Oil Factories at Bombay and Kozhikode run by the Bombay and Madras Governments respectively. In addition to these certain institutions run by the Central Government carry out manufacturing operations of biological products like vaccines and sera over and above their normal functions of medical research, testing, diagnostic work etc. Similarly, State Government institutions carry out manufacture of biologicals and some synthetic drugs in addition to their normal functions of research, testing etc. The following table shows the capital invested, value of raw materials consumed, total sales, labour employed etc., in the major Government institutions:—



सत्यमेव जयते

TABLE NO. 5.—THE CAPITAL INVESTED, VALUE OF RAW MATERIALS CONSUMED, TOTAL SALES, LABOUR EMPLOYED ETC., IN MAJOR, CENTRAL AND STATE GOVERNMENT FACTORIES.

Name of Government factory	Total Capital invested in Rs.	Sale value of finished products in 1952 in Rs.	Value of raw materials consumed in 1952 in Rs.		Labour employed		Expenditure on advertisement in 1952		Remarks	
			Indigenous	Imported	Tech.	Non-Tech.	Total	Total in Rs.		% of total sales
I	2	3	4	5	6	7	8	9	10	11
<b>BOMBAY:</b>										
1. Indian Penicillin Plant	44,50,000	30,61,000	1,23,000	14,70,000	5	80	85	Nil	Nil	
2. Government Oil Factory	2,10,000	3,00,000	1,09,300	..	3	11	14	1,936	0.64	
3. Government Medical Stores Depot	2,40,000	10,00,000	7,00,000	..	13	57	70	Nil	Nil	
4. Haffkine Institute	48,25,000	20,00,000	N.A.	N.A.	70	500	570	..	..	
<b>WEST BENGAL:</b>										
5. Government Quinine Factory, Mungpoo	*3,00,000	15,00,000	14,00,000	..	12	163	175	N.A.	N.A.	
<b>MADRAS:</b>										
6. Government Quinine Factory, Naduvattam	24,91,000*	10,07,000	7,00,000	..	13	50	63	2,406	0.24	*Excluding Capital on plantations.



I	2	3	4	5	6	7	8	9	10	11
7. Government Shark Liver Oil Factory, Kozhikode .	3,15,900	3,57,200	1,60,000	..	2	43	45	30,660	8.6	
8. Government Medical Store Depot . . . . .	4,93,000	12,00,000	9,00,000	..	16	124	140	Nil	Nil	
9. The Veterinary Biological & Research Institute, Rani- pet . . . . .	7,00,000	5,000	1,49,100	..	31	64	95	Nil	Nil	
UTTAR PRADESH 10. Government Opium Fac- tory, Ghazipur . . . . .	@ 8,80,000	12,05,000	3,33,300	..	16	400	416	Nil	Nil	@On Alkaloid factory alone.
11. Indian Veterinary Res- earch Institute, Izetnagar .	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	
TOTAL . . . . .	1,48,14,900	1,16,35,200	45,74,700	14,70,000	181	1,492	1,673	35,002	3.16 (Average of 3 institu- tions).	

NOTE:—

(1) Government Quinine Factory at Anamalai (Madras State), Government D.D.T. Factory (Delhi) and Government Penicillin factory at Pimpri are under construction.

(2) S. Nos. 1, 2, 5, 6, 7, 9 and 10 are registered under the Industries (Development and Regulation) Act, 1951.

## 2. Government Medical Stores Depots.

2.1. Government Medical Stores were set up in some of the important cities in the country during 1870 with the primary object of ensuring the supply of drugs, instruments and appliances etc., of uniform quality and pattern for the Army in India. Of these, the stores now left in the Indian Union are located at Madras, Bombay and Calcutta. After the partition of India in 1947, a new depot was created at Karnal in lieu of the one in Lahore, which went over to Pakistan. Until 1894, these Depots were under the control of the Provincial Surgeons General, but after that date they were taken over by the Government of India under the charge of the Director General, Indian Medical Services and Army Department. Originally, these Depots were mere stores for drugs and medical and surgical equipment received from abroad or purchased from the Indian Market, for supplying the military and semi-military organisations. In course of time, the sphere of activity of these Depots extended as the Civil Medical Departments of Local Governments, Municipalities, District Boards and some princely States also started indenting their requirements on them. With the extension of their areas of supply, the Depots at Madras and Bombay gradually commenced the preparation of pharmaceuticals and the repairs of instruments and appliances. The preparation of pharmaceuticals consisted mainly of galenicals and was undertaken as the raw materials which were going outside the country for their preparation, could be utilised to produce them in the country at a cheaper price than that at which these products were being imported. The Medical Stores Depots fulfilled these expectations and turned out preparations upto the B.P. Standard at prices at which the European market could not supply. In 1910, an enquiry was instituted by the officers incharge of the Medical Stores to ascertain if the Government was getting a fair return for the money spent on the Medical Store Depots and if the policy of manufacturing drugs was right in view of the development of the drug manufacturing industry in India. The view of the Committee was that the manufacturing activity was profitable and should continue. The Industry had not developed to such a stage as to do away with the production in these depots. Soon after this, World War I broke out and the Medical Store Depots came in to play a very important role in the supply of Medical Stores to the forces at various theatres of war like East Africa, Mesopotamia, and Egypt. The internal demand on these Depots also increased several-fold as during this period many ships carrying Medical Stores to India were sunk in the seas by enemy action and the Depots came in handy in equipping various new institutions in the country, hospital-ships, ambulance trains etc. In 1917, a further demand was made on the resources of the Medical Stores by the decision of the Government that all schools, colleges, laboratories and other scientific institutions which formerly submitted their indents to the Director General, Indian Stores Department, London, should, in future, obtain their supplies of such articles as were available in these Depots. During this period, Madras and Bombay Medical Stores increased the out-put of their factories considerably.

2.2. The Medical Stores were able to turn out preparations at a cost less, in many instances, than the local manufacturers, as they had a steady demand and took advantage of low rates for the bulk

purchases of raw materials. The arrangement was considered as a co-operative venture between Army and the Civil Institutions from which both derived equally substantial benefits. In spite of the fact that civil institutions were not compelled to obtain their stores from the Depots, indents were increasingly made by them on the Stores.

2.3. The representatives of manufacturing firms in Calcutta and Bombay protested to the Drugs Enquiry Committee set up by the Government of India in 1930 very strongly against the Government manufacturing tinctures, extracts etc., which they considered as an intrusion into the sphere of activity which did not properly belong to the Government and hindered the growth and expansion of the Drug Industry in the country. This Committee collected information concerning the production of galenicals of the entire country and compared it with that of the Medical Stores Depots and concluded that they were no great rivals to the drug trade as regards these preparations, since the quantities produced by them were small compared to the total quantity manufactured by the rest of the factories. They also observed that the Medical Stores Depots were manufacturing and supplying to the civil indentors under the same conditions as private manufacturers and there was no unfair competition. On the other hand, the prices of Medical Stores Depots were sometimes above the current prices in the market and complaints were being received from the various indentors on this point. They considered it yet premature to say that the State enterprise in this direction had outgrown its necessity and their continuance was necessary as a stand-by in case of war or a sudden stoppage of foreign imports, and as a check to prevent profiteering by private firms. They also suggested that as local manufacturing progresses and good quality drugs are obtainable at a cheaper rate, the manufacturing activity of the Depots should be gradually reduced. On principle, the Government should not compete with private concerns manufacturing medicinal preparations.

2.4. With the creation of the Armed Forces Medical Store Depots during World War II, the Medical Store Depots were divested of the responsibilities of supplying the stores to military and semi-military organisations. Their activities were, therefore, restricted to supplying the civil medical requirements of the Central Government and the various State Governments. The Depots were brought under the administrative control of the Health Ministry. During this period, the supply position of medical stores was very difficult due to a general shortage of supply in the world and the depots in some cases were able to supply only about 45-50 per cent. of indentors' demands. Complaints were received from various indentors and severe criticisms were made at the time of the Third Health Ministers' Conference in 1950. Vigorous steps were then taken to improve the supply position by altering the provisioning methods and by the year 1951-52, the supply position against demands reached about 90-95 per cent.

2.5. *Stores Activities.*—Each of the medical stores is under the charge of a Deputy Assistant Director General. The Medical Stores Depots at Calcutta and Karnal function only as supply depots. The

former caters to the demand of Assam, Bihar, Orissa and adjoining Railways, while the latter supplies the needs of Punjab, PEPSU, Himachal Pradesh and Delhi. The Medical Stores Depots at Bombay and Madras meet the needs of their respective States and adjoining States and Railways. In addition, the Part 'C' States also draw their supplies from the nearest Depots. States like Hyderabad, Madhya Bharat and Jammu and Kashmir obtain their requirements only partially from the Medical Stores. The total overhead charges of running the Medical Stores Department are about Rs. 31 lakhs of which about Rs. 22 lakhs account for the establishment charges and the balance direct and indirect overheads. The above sums are recovered by way of departmental charges which are included in the Priced Vocabulary of the Medical Stores. The requirements of the Medical Stores Depots are estimated annually and procured through the Director General of Supply and Disposals (D.G.S. & D.) and articles which are not available within the country through the Director General, Indian Store Department (D.G.I.S.D.), London, who arranges for their purchase and supply. To safeguard the interests of the indentors, the articles received by the Depots are first tested for their quality at the laboratories attached to the Medical Stores Depots at Bombay and Madras. Bacteriological examinations, for which there are no facilities at the laboratories attached to the Stores at Madras and Bombay, are carried out at the Central Drugs Laboratory, Calcutta. A catalogue of the articles supplied by the Depots known as the P.V.M.S. (Priced Vocabulary of Medical Stores) is being maintained. This is being revised from time to time to include the commonly used drugs and chemicals of recent invention and to delete obsolete ones and thus kept up to date. The Medical Stores Depots at Bombay, Madras and Calcutta, stock in addition to normal requirements certain gift stores received from United Nations International Children's Emergency Fund (U.N.I.C.E.F.), Technical Co-operation Mission (T.C.M.) and World Health Organisation (W.H.O.). These are, however, temporary activities of the Depots and their magnitude depends upon the volume of supplies received from the above organisations.

*2.6. Manufacturing Activities.*—The Medical Stores Depot at Madras caters to the needs of the Government Hospitals and certain non-government hospitals and public and missionary institutions of Madras State and to Central Government Institutions including Railways. In addition to the stores side, it has a manufacturing department where galenicals, disinfectants, insecticides and solvents like ether are produced and a processing department, where drugs such as aspirin, sulphanilamide etc., are tabletted and certain ointments, pastes and creams are prepared. A laboratory is also attached to this Store, where all the raw materials required for the manufacture of drugs and finished products are tested. This laboratory, in addition, carries out the testing of medical stores procured by this Depot and other Depots for meeting the demands of the indentors. The capital value of this factory has been estimated at Rs. 4,10,000 excluding the value of land, which is estimated at Rs. 83,000. The value of raw materials consumed is about Rs. 9 lakhs and the sale value of finished products is Rs. 12 lakhs. The factory employs 140 persons of whom 16 are technical personnel.

2.6.1. The Bombay Medical Stores Depot caters to the requirements of Government and non-government institutions which are enrolled as regular indentors of this Depot. Like the Madras Depot, in addition to its Stores activities, it has a manufacturing department where galenicals, disinfectants etc., are produced and drugs such as sulphanilamide, aspirin, nicotinic acid etc., are processed into tablets. The capital investment of the factory has been estimated at Rs. 2,40,000 excluding the value of the land. The total value of raw materials consumed annually is Rs. 7,00,000 and the total sale value of finished products is about Rs. 10,00,000. The total labour employed is about 70, of whom 13 are technical personnel.

2.7. The Medical Stores Depots at Bombay, Madras and Calcutta were visited by us during our tours and their manufacturing and stores activities studied.

2.7.1. We feel that in Bombay and Madras Stores, where production of pharmaceuticals is also undertaken, the equipment used is out of date and the products made consist of common items, which are also produced by private manufacturers. The procedure employed in obtaining raw materials and equipments is very cumbersome and not conducive to the efficient running of the factories. For instance, indents for the supply of raw materials have to be placed on the Director General of Supply and Disposals in the same way as on other medical stores, and their procurement takes not less than 15 months normally and sometimes about 20 to 24 months. The only way the factories can overcome this delay in the supply of raw materials is by maintaining a huge stock locking up a large capital. Maintenance of huge stocks also results in a certain amount of deterioration and consequent writing off of large sums of money. The procedure adopted is, therefore, not considered conducive to the efficient running of any factory especially for the manufacture of pharmaceuticals. The Local Governments also complained, that the prices charged by the Medical Stores were much higher than those prevailing in the market, and the time taken for delivering the stores was much longer. Along with the indents for the supply of the stores, the non-Government indentors had to deposit an advance equivalent to the value of the goods indented. Very often many of the indented articles were not supplied at all. The small hospitals run by District Boards and other similar institutions did not have enough funds to buy these from other sources, as all their money was locked up as an advance with these indents and many of them had to go without the supply of their medicinal stores. The indentors on the list of these Depots did not appear to get any special advantage in drawing their requirements from the government Medical Stores Depots. The production of the depots is in no way larger than that of other private concerns to accrue the advantages of bulk purchases of raw materials, and economies of large scale production. Added to these, the anti-quoted equipment, cumbersome procedure of obtaining raw materials, increase their inefficiency and cost of production. Because of their usefulness in an emergency like war, famine, earthquake etc., when their production could be stepped up to maintain prices at a steady level, in spite of any sudden increase in the demand, the possibility of handing them back to the Army authorities who usually deal with such emergencies was considered. But we were informed that the Defence Organisation had no interest in taking

over these Depots as they had already set up a parallel organisation for procuring their stores.

2.7.2. Since Government have participated in the manufacture of pharmaceuticals, which is a key industry, through these Depots, the Committee do not consider it advisable to scrap them straightaway. The manufacturing activities should be reorganised and the method of management changed to conform to commercial practices. The antiquated equipment should be replaced by modern equipment and in addition to the existing manufacturing activities, production of essential items like fine chemicals, glandular products and vitamins which are not being made adequately by the private sector should be taken up. For example, the Government Stores Depot at Bombay can take up the manufacture of glandular products including the hormones as they are more favourably situated close to a very big slaughter house which could supply the required glands, tissues etc. Similarly, the Madras Depot could probably take up the manufacture of vitamins and other related products. The choice, however, of the new products should mainly depend upon the feasibility of such development and availability of raw materials, power, market etc.

2.7.3. *Supply of Stores.*—The prices charged for the Stores by the Depots depend upon the rates at which they are procured by the Director General of Supply and Disposals in respect of indigenous items and the Director General, Indian Stores Department in respect of imported articles. In the case of imported stores, the prices charged by the Depots include the cost of freight, customs duty plus 20 per cent. as departmental charges, and in the case of indigenous stores 5 per cent. on account of inland freight plus 20 per cent. as departmental charges resulting in a surcharge of 26 per cent. In addition, all transit and packing charges from the Depots to the destination of the indenter have to be paid by the indenter. In several cases the prices thus arrived at become uneconomical. Some items stocked by the Depots are obtained on a Rate Contract through the Director General, Supply and Disposals and they are not permitted to obtain such stores at better rates from other firms. In the case of such stores the price is considerably higher than that at which the indentors would have been able to obtain if they had purchased them directly from the firms.

2.7.4. Another important factor is that the State Governments are allowed to obtain their requirements of imported supplies direct for the use of their medical and public health departments without paying any customs duty under the provisions of the Constitution. We were informed that the Central Board of Revenue, who were requested to grant a similar concession in respect of the Central Medical Store Depots, have refused to grant them the same concession. This will mean that the rates of all imported articles supplied by the Central Medical Store Depots will include customs duty which the States will be able to avoid, if they import the stores direct. Large number of items whose value is less than Rs. 2,000 are procured directly by the Depots and supplied to the indentors after adding the usual 26 per cent. of surcharge. Since these purchases are made more or less on a retail basis, the advantages of bulk purchases do not accrue to the indentors while on the other hand, with the 26 per cent. surcharge, the prices of the stores are higher than that at which the indentors could have procured them directly.

2.7.5. These factors have contributed to the higher rates charged by the Depots and hence their growing unpopularity. Certain State Governments are already keeping out and other Governments are thinking of obtaining their requirements directly instead of through the Depots. Their working is, therefore, becoming more and more uneconomical. Under these circumstances, we do not see much future for the stores activities of these Depots and feel that they may ultimately have to be given up. The only alternative appears to be to hand over the stores activities of the Depots to the respective State Governments consistent with the commitments of the Central Government. But in case the State Governments are not in a position to take over the Medical Stores, there may be no choice but to close them down.

### 3. Opium factory.

3.1. Opium is the latex obtained by incision from the unripe capsules of the poppy (*papaver somniferum*) which is cultivated in warm temperate regions of Asia, Europe and North Africa. The plant is reported to have been cultivated in this country since the days of the Mughals, who used opium as a source of revenue. The East India Company also traded in this commodity and rights for buying the latex and manufacturing opium were leased by them to contractors for a heavy fee. This system was abolished and the first State monopoly for production of opium was introduced in 1797 by Lord Cornwallis in the interests of Government revenues and all cultivators of poppy were compelled to sell opium only to the Government. In 1820, for processing this, opium factories were set up in Ghazipur and Patna. During this period, India had a flourishing trade in opium with China, the exports to that country being about 1000 tons per annum. The cultivation of poppy extended to about 6 lakhs acres in the States of U.P. and Bihar and 3 to 4 lakhs acres in the Malwa States. In addition, the private States of Baroda, Ujjain, Udaipur, Kotah and Diwas had their own opium cultivation and factories. The cultivation of poppy in Bihar was completely stopped and the Patna factory closed down in 1910 as a voluntary stoppage by India of her flourishing trade with China at a loss of revenue of several crores of rupees.

3.2. At present, poppy cultivation is confined to 9 districts in Uttar Pradesh, 2 districts in Madhya Bharat and 4 districts in Rajasthan. Small cultivations also exist in Himachal Pradesh and Bilaspur. The acreage under poppy in the different States during the last 5 years for the manufacture of opium is as follows:—

TABLE NO. 6—THE AREAS UNDER POPPY CULTIVATION IN DIFFERENT STATES  
(IN ACRES)

	1948-49	1949-50	1950-51	1951-52	1952-53
Uttar Pradesh . . .	18,956	17,150	22,909	33,776	30,759
Madhya Bharat . . .	31,008	20,948	25,984	10,263	30,017
Rajasthan . . . . .	14,904	10,796	18,597	9,961	20,804
Himachal Pradesh . .	4,559	2,536	2,234	2,197	2,046
Bilaspur . . . . .	287	62	191	168	87
TOTAL . . . . .	69,714	51,492	69,915	56,365	83,713

3.3. Opium is at present purchased from the cultivators at about Rs. 16/8/- per lb. In addition, a quality bonus for high morphine content and a quantity bonus for a yield exceeding 6 seers (13.2 lbs.) per bigha is allowed. So far, the issue of a quality bonus is the only step taken by Government to induce cultivation of better grades of poppy. The other bonus is mainly to dissuade cultivators from indulging in surreptitious sales of opium for illicit traffic. It is essential to set up experimental plantations with a view to (i) increase the yield of opium, (ii) render technical advice, (iii) supply better grades of seeds, and (iv) demonstrate improved methods of cultivation to help the cultivators to improve the produce of their plantations. As the first lancing contains a higher percentage of alkaloids than the subsequent lancements, the cultivators are induced to collect these separately. These are also processed separately and sold as two different grades.

3.4. The Opium Factory at Ghazipur with an estimated capital investment of Rs. 160 lakhs consists of 2 sections: (a) the main Opium Factory and (b) the Alkaloid Factory.

3.4.1. *The main factory.*—This consists of 8 large godowns capable of storing about 3,000 tons (80,000 maunds) of opium, 21 godowns for storing other accessories, a manufacturing and caking room and a store for processed opium. There are 13 store-vats capable of handling about 900 tons (24,000 maunds) of opium at a time. The opium is beaten down to an uniform consistency by stirring manually with ladles, dried by exposing it to sunlight and with the help of several huge hand-operated screw presses, pressed into blocks of 1 lb. each. The factory employs about 400 labourers. The processed opium contains on an average 11 per cent. of morphine and 3 per cent. of codeine and a small percentage of other alkaloids. The opium produced in this factory is partly exported for medicinal and scientific purposes, partly used in the adjoining alkaloid factory for production of opium alkaloids and its salts, and partly sold for oral consumption in the country through the State Governments. The price of exported opium is calculated in terms of units of morphine content. The following table shows production and exports of opium during the last three years:—

TABLE NO. 7—PRODUCTION AND EXPORTS OF OPIUM DURING 1950-51 TO 1952-53

Year	Pro- duction (tons)	Exports									
		U.K.		France		U.S.A.		Others		Total	
		Qty. (ton)	Value (in thous- and Rs.)	Qty. (ton)	Value (in thous- and Rs.)	Qty. (ton)	Value (in thous- and Rs.)	Qty. (ton)	Value (in thous- and Rs.)	Qty. (ton)	Value (in thous- and Rs.)
1950-51	407	161	10,221	45.0	2,986	94	6,442	7	450	307	20,099
1951-52	263	112	7,380	30.5	2,074.5	93	7,465	5	415.5	240.5	17,335
1952-53	221	64	5,363.5	15.0	1,129	33	3,200	..	4.5	112	9,697



Sales for oral consumption within the country are being progressively reduced at a rate of 10 per cent. over the supplies made during the year 1948-49. By the year 1958-59 it is intended to stop completely the sale of opium for oral consumption within the country. The following table shows the quantity of opium sold to each State Government for sale for oral consumption during 1953-54.

TABLE NO. 8—THE QUANTITY OF OPIUM SOLD TO EACH OF THE STATE GOVERNMENTS FOR SALE FOR ORAL CONSUMPTION DURING 1953-54

Name of the State	Quantity in lb.
<b>PART 'A' STATES</b>	
1. Assam	352
2. Bihar	5,252
3. Bombay	9,582
4. Madhya Pradesh	6,580
5. Madras	5,627
6. Orissa	23,727
7. Punjab	16,925
8. Uttar Pradesh	25,984
9. West Bengal	26,863
<b>PART 'B' STATES</b>	
1. Hyderabad	8,462
2. Madhya Bharat	24,600
3. Mysore	996
4. Pepsu	18,696
5. Rajasthan	46,658
6. Saurashtra	6,789
7. Travancore-Cochin	3,091
<b>PART 'C' STATES</b>	
1. Ajmer	2,132
2. Bhopal	3,278
3. Bilaspur	..
4. Coorg	..
5. Delhi	2,864
6. Himachal Pradesh	2,626
7. Kutch	2,362
8. Manipur	43
9. Tripura	396
10. Vindhya Pradesh	1,802
<b>PART 'D' STATES</b>	
1. Andamans	576
<b>TOTAL</b>	<b>2,46,263</b>

3.4.2. When we visited this factory, we were surprised to find that no attempt had been made to mechanise any of the operations involved and the methods adopted had remained much the same as were introduced during its period of inception in 1820. The management mentioned that the present policy of Government was not to mechanise such operations as it would result in retrenchment of the labour employed. We feel that this policy has been wrongly applied in this case. The stirring by hand of such a viscous mass as the crude opium to a homogeneous consistency is not a simple operation. We found during our visit several labourers on this hard job dripping with perspiration in the sweltering heat of Ghazipur. In the present day, when diverse types of gadgets for stirring and mixing are available, it is strange that the factory should continue to adopt this crude method on the plea of avoiding unemployment. We consider the present method inhuman, and would recommend mechanisation of such operations without further delay. It is a mistaken notion to consider that mechanisation of such operations can deprive men of their employment. On the other hand we feel that if such operations are mechanised, it will lead to better employment of the same number of labourers in other branches of the department as a result of an increased output in the factory. Government enterprises should give in all respects a lead to the private enterprise specially where hardships to labour are involved and adopt modern methods of manufacture. In a product like opium, which is a monopoly of Government, competition from the private sector is completely cut off, and the high cost of production, when such operations are carried out manually, usually remains unnoticed. Therefore, this aspect will have to be viewed on humanitarian grounds and improvements carried out. Another crude operation that we noticed being carried out manually in this factory was the bricketting of the processed opium with the help of hand-operated screw-presses. This is again an outmoded device which involves hard manual labour and should be replaced as early as possible with a pugmill or similar device. This will also enable the factory to produce blocks of uniform weight and avoid the need of checking the weight of each block individually as is being done at present by a large number of labourers with scales in their hands at the succeeding stage.

3.4.3. We also noticed that the opium was being sun-dried by exposing it to the sun in open trays on a stone platform thereby increasing the chances of its contamination with dust and dirt. By drying with artificial heat, not only a better control on its moisture content is possible but also will make the factory independent of such an uncertain factor as sunlight during the monsoon in a place like Ghazipur, and avoid contamination with dirt. We were told by the Management that the sun-drying developed a special flavour in the opium which artificial heat could not and sundried opium was preferred to opium dried by artificial heat in places where it was used for oral consumption. This view is quite contrary to the desire of Government of discouraging the habit of opium eating among the people of the country. The Government had instituted a programme of progressively reducing the quantity of opium supplied for such purposes and completely stopping its sale for oral consumption by 1958-59. Under the circumstances, there was no point in catering to the taste of opium addicts by adopting methods which would increase their flavour. The factory should concentrate on adopting methods

that would improve its quality like its total alkaloid content, prevention of contamination with dirt and dust, regulated moisture content etc., which would improve its value for industrial and medicinal purposes and not adopt methods to improve its flavour. We also found that a large labour force was employed to pick out foreign matter from the sundried opium and this we were told, had to be adopted as complaints were being received from foreign countries of contamination of the product. This again, we feel, could be completely avoided by employing mechanical means during the various stages of preparation.

3.4.4. We also noticed, that elaborate arrangements existed to ensure that the large number of labourers employed washed out all opium sticking to their hands and feet with which they came into contact during the various manual operations, and a large Watch and Ward force was employed to see that no opium was being carried away clandestinely by them. All this would be minimised by mechanising the operations involved and reducing the number of handlings of the product by the labourers.

3.4.5. *Alkaloid factory*.—Until 1942, crude morphine was being extracted in small quantities of about 150 lbs. per year in this section of the factory from waste products of the main opium factory like floor-washings, vat scrappings, contraband opium etc. The factory employed about 20 labourers and operated hardly for 3 months in the year. The construction of a full-fledged alkaloid works was undertaken in 1942 at a cost of Rs. 8 lakhs and brought into full production only in 1948. It employs 400 labourers and 16 technical personnel. Its present capacity is estimated at 2,000 lbs. of alkaloids per annum working 1 shift a day. Semi-refined morphine is extracted from opium from which refined morphine and its salts and codeine and its salts are prepared. The annual capacity of the factory for these products working one shift a day is as follows:—

	lbs.
Finished codeine and its salts	1,200
Finished morphine and its salts	250
Finished ethyl-morphine hydrochloride	100

The quantity of codeine and its salts produced during the last 3 years is as follows:—

Year	lbs.
1949-50	853
1950-51	1190
1951-52	2167

The following salts are being produced and marketed by the factory:—

Morphine B.P.C.	Ethyl Morphine Hydrochloride B.P.C. (Dionine)
Morphine Hydrochloride B.P.	Narcotine B.P.C.
Morphine Sulphate B.P.	Narcotine Hydrochloride.
Morphine Acetate B.P.C.	Cotarnine Hydrochloride B.P.C.
Morphine Tartarate B.P.C.	Papaverine B.P.C.
Codeine B.P.	Papaverine Hydrochloride B.P.
Codeine Phosphate B.P.	Thebaine.
Codeine Sulphate U.S.P.	

Some of these salts are also exported to other countries. The quantities of these salts sold within the country and exported during the last three years are as follows:—

TABLE NO. 9—QUANTITIES OF OPIUM ALKALOIDS AND THEIR SALTS SOLD IN INDIAN BY THE ALKALOID FACTORY, GHAZIPUR AND EXPORTED

Year		Sold in India (lbs.)	Exported (lbs.)
1949-50	. . . . .	1,341	16
1950-51	. . . . .	1,430	374
1951-52	. . . . .	1,166	1,479

3.4.6. This factory is comparatively more modern and better equipped. But we noticed that the production of the various salts is still being carried out in a semi-commercial scale and we were told that there was not enough demand for these salts for undertaking production on a fully commercial scale. This appears to be mainly because its activities are so little known to the markets within and outside the country. The products of the factory will have to be advertised in Indian and foreign scientific and trade journals if markets for the products are to be improved. We found that no expenditure was being incurred by the factory on advertising its products. This, we consider, is false economy and should be rectified.

3.4.7. Another cause responsible for the low offtake of this factory is the lack of commercial methods of marketing. At present for all purchases, the money has to be paid by the consumers in advance through a Treasury. The goods when despatched are not sent by post but as a railway parcel by passenger train. Additional charges are being levied for packing. All these tire the patience of the consumer and increase the cost. The consumer, therefore, prefers to buy them from sources other than the Government factory. If at least some wholesale dealers or agents are appointed who take upon themselves all the responsibility and offer credit and other facilities to the trade and push the sale of the products, the offtake of the factory would improve severalfold.

#### 4. Penicillin Factory.

4.1. In order to explore the possibilities of the manufacture of penicillin and other drugs, the Government of India, in 1946 and again in 1948, deputed technical teams headed by Major General S. S. Sokhey to visit the factories in the U.K., U.S.A., Canada and Europe. In their reports, they recommended that the manufacture of 3.6 million mega units (3,600 billion units) per annum of penicillin should be undertaken by the Government. In January 1949, the Government of India considered the above recommendation and decided to set up a State-owned Concern with a company form of management for the manufacture of this drug and negotiations with Messrs. Karnbolaget of Sweden for technical assistance were started.

4.2. An agreement was entered into with this firm in March 1949 and it was hoped that a factory would be set up in less than two

years. But early in 1950, Messrs. Karnbolaget entered into an agreement with Messrs. Mercks of U.S.A. to avail themselves of the more advanced technical processes for the manufacture of penicillin used by the latter firm. Under this agreement, secret processes divulged to Messrs. Karnbolaget by Mercks, and patents made available to them through the same firm could not be made available for the Indian Penicillin factory. To overcome this difficulty, the Government of India entered into negotiations with M/s. Mercks of U.S.A. and Messrs. Karnbolaget for a tripartite agreement.

4.2.1. While the above negotiations were going on, an offer of monetary and technical assistance for a Penicillin Project in India was received from the World Health Organisation and the United Nations International Children's Emergency Fund. The pros and cons of entering into tripartite agreement with Messrs. Karnbolaget and Messrs. Mercks and of accepting the offer of monetary and technical assistance from World Health Organisation (W.H.O.)/United Nations International Children's Emergency Fund (U.N.I.C.E.F.) were examined in detail and ultimately, the Government of India decided to set up the Penicillin Factory in collaboration with W.H.O./U.N.I.C.E.F. An agreement in this connection was concluded on the 24th July, 1951 between the Government of India, the W.H.O. and the U.N.I.C.E.F. Under this agreement, the Government are to provide the land for the factory and other buildings necessary for running it and also fittings, administrative offices, laboratories, pilot plant, workshop and other services such as steam plant, electric substation, sewage disposal and water etc., which are estimated to cost about Rs. 1,30,00,000. The U.N.I.C.E.F. are to supply all the imported equipment estimated at \$8,50,000. W.H.O. are to provide technical assistance estimated at \$3,50,000. From 1st July 1953, the responsibilities in respect of the project so far as the W.H.O. is concerned has been taken over by the United Nations Technical Assistance Administration.

4.3. The factory is planned to produce 3.6 million mega units (3,600 billion units) of Penicillin per year to start with, raising to 9 million mega units (9,000 billion units) per year. The method of production to be adopted will be fermentation of cornsteep liquor by means of penicillin mould to obtain penicillin in solution and its extraction with organic solvents. A site at Pimpri, near Poona, has been selected for the factory and the construction of factory buildings and residential buildings at the site is in progress. Orders have been placed by the U.N.I.C.E.F. for a major portion of the plant and equipment and consignments have started arriving. Training of technical personnel has been arranged. The factory is expected to start production soon.

4.4. In view of the rapid developments both in the technique of manufacture and in the discovery of new antibiotics, the Committee would like to emphasise the need for establishing a well-equipped research laboratory and a pilot plant at this factory for carrying out investigations side by side with manufacture to keep pace with the rapid developments in the field of antibiotics. The pilot plant will help to work out the optimum conditions for the main plant without having to carry out large scale trials on the main plant itself, which will be expensive.

4.5. The Penicillin Factory under installation is designed to produce ultimately 9 million mega units (9,000 billion units) of penicillin per year against the country's estimated requirements of approximately 20 million mega units (20,000 billion units). It is reported that with the use of improved strains of penicillin mould, the proposed capacity could be further increased to 15 million mega units (15,000 billion units) without any major additions to the plant. This would mean that the major portion of the existing demand would be ultimately met by this factory. But it is very likely that the demand will increase further by the time this production is actually achieved. To plan for meeting the balance, the Government should either encourage the private sector to manufacture it or increase the capacity of this factory further.

4.6. The manufacture of other antibiotics particularly streptomycin should also be undertaken in this factory. If due to some reason, it is not possible to produce the entire estimated requirements of 10,000 kg. of streptomycin in this factory, then the private sector should be encouraged to produce the balance.

4.7. As the manufacture of penicillin needs certain chemicals, whose production will also have to be undertaken in this factory, it may be economical to extend the activities of this factory further and undertake, in addition, production of synthetic antimalarials, sulpha drugs, other chemotherapeutic products and vitamins. By organising the manufacture of all these products at this factory, the cost of establishment for research, pharmacological bioassay, administration and other overheads will be divided among all these products, making their incidence on cost of production comparatively lower, instead of having separate plants for their production at different places. Moreover, with the existing shortage of trained personnel, it would be advisable to concentrate these efforts at one place as the supervision of the existing small number of highly trained personnel for the development of production of all these products will become possible. This will also help to train more men on such specialised jobs.

4.8. *Bottling plant.*—To meet the immediate requirements of penicillin in the country, a Penicillin Bottling Plant with a capacity of 20,000 vials a day and on an average 2.4 million mega units (2,400 billion units) of penicillin per year has been set up in a new building in the Haffkine Institute compound in Bombay at a capital cost of about Rs. 44.5 lakhs and is functioning since 28th May 1951. Foreign penicillin, imported in bulk, is being bottled at this plant. It meets all Government requirements and also a part of the requirements of the public.

## **5. D.D.T. Factory: (The Hindusthan Insecticides Ltd.).**

5.1. The control of malaria, which has been engaging the attention of the Central and State Governments for a considerable time, has been made simpler and less costly with the advent of D.D.T. The different State Governments in India have been extending spraying of D.D.T. in their malarial tracts during the past few years. But a serious obstacle in the way of a rapid expansion of this measure has been the difficulty of securing adequate quantities of this insecticide, which is, at present, mainly imported. The Government of India,

therefore, have decided to establish a D.D.T. factory in India with a capacity to produce 700 tons of D.D.T. per annum and a joint plan of operations, in this connection, has been concluded between the Government of India, World Health Organisation (W.H.O.) and United Nations International Children's Emergency Fund (U.N.I.C.E.F.) on the 19th July, 1952. Under this agreement, the U.N.I.C.E.F. will supply all imported equipment involving an expenditure of about \$2,50,000. W.H.O. will arrange and provide all technical assistance for the factory involving an expenditure of about \$1,00,000. The Government of India will arrange for the provision of land, buildings, steam, water, electricity etc., at an expenditure of Rs. 22,45,000. A site adjacent to Messrs. D.C.M. Chemical Works, Delhi, has been chosen. The D.C.M. Chemical Works have agreed to provide the required steam and water supplies, as well as the necessary sulphuric acid, alum and chlorine for the factory at reasonable prices.

5.2. It has been decided that the factory will be managed by Government through a private limited company registered under the Indian Companies Act, with a Board of Directors. The factory is expected to go into production in the near future.

5.3. To keep pace with the rapid developments in the field of insecticides in this case also, a research unit and a pilot plant should be provided to carry out investigations on new types of insecticides and conduct experiments on their production.

5.4. The country's requirements of insecticides for antimalarial operations alone have been estimated at 8,000 tons per annum upto 1956 and, thereafter, at 5,500 tons per annum. The capacity for production of Benzene Hexachloride (B.H.C.) and D.D.T., either in existence or expected to come up shortly, is estimated at 2,000 tons per annum. In the Government factory that is being put up at present, the plant and equipment is designed to produce only 700 tons per annum. But in the building a provision for a duplicate unit to be put up and increase the capacity of the factory to 1,400 tons per annum has been made. It is also reported that there will be no difficulty of obtaining chlorine, sulphuric acid, steam etc., from the neighbouring factory of Messrs. D.C.M. Chemical Works to meet the requirements of this increase in production. Even if this increased production is achieved, there will still be a considerable gap between the production and demand. The Committee, therefore, recommend that the Government should either encourage the private sector to manufacture it or themselves put up a second unit for its production in any suitable place in the country, where the required raw materials and power are available.

## 6. Quinine Factories.

6.1. Cinchona, a native plant of Peru and Bolivia in South America, and the source of quinine, was introduced into India as an experimental plantation in the Nilgiris in 1860 and in the Darjeeling District in 1861. The plant was found to thrive well and by 1871, the area under Cinchona cultivation had increased in the Nilgiris to 2,404 acres, and in Darjeeling to 1,939 acres. Factories were started during this year at Naduvattam in the Nilgiris and Mungpoo in the Darjeeling

District for the extraction of the total alkaloids which continued till 1887, when quinine sulphate was manufactured for the first time in the factory near Darjeeling. The factory in Nilgiris followed suit in 1890 and started producing quinine salts.

6.2. Attempts by Government to encourage private cinchona plantations did not materialise specially in competition with tea and coffee. The Government had, therefore, to develop the cinchona plantations entirely as a State enterprise, as a public welfare measure. The financial aspect gradually improved and profits began to be made by the State Governments, from the year 1912. Large profits were made particularly by the Bengal Government during the First World War. As a result of the experiences of World War I, when supplies of quinine in the country were found to be quite inadequate, an attempt was made by the Central Government in 1920 for centralising the activities of the Cinchona Departments of the two States by taking them over under the Government of India for full utilisation of the potential capacities of the existing plantations, which were estimated to be very large; but this attempt was unsuccessful as the Government of Bengal were not prepared to transfer their plantations to the Central Government.

6.3. A shortage of supply was again felt during World War II and there was a move for the expansion of the existing plantations in Bengal and Madras and for starting fresh plantations in Assam. These schemes were encouraged and actively helped by the Central Government. As a result of this, the area of cinchona plantations in Bengal and Madras was considerably expanded and new plantations started in Assam. The following table shows areas under cinchona cultivation in 1939 and 1952:—

TABLE NO. 10—AREAS UNDER CINCHONA CULTIVATION IN 1939 AND 1952

Name of Plantations	Location	Area in 1939 (acres)	Area in 1952 (acres)
Madras . . .			2,118
Nilgiris . . .	At Naduvattam about 21 miles from Ootacamund . .	1,279	2,381
Anamalai . .	About 75 miles from Coimbatore . .	839	6,607
Kadambari . .	Adjacent to the above plantations . .	..	314
West Bengal . .			7,569
Mungpoo . .	Darjeeling Distt. .	3,283	3,125
Munsong . .	Do. . .	4,175	4,106
Rongo . .	Do. . .	111	1,282
Latpanchor . .	Do. . .	..	665
Assam . . .			..
Umsaw and Nongpoh.	Khasi Hills . .	..	700
Total		9,687	19,180



6.4. During recent years there has been a sharp fall in the sales of quinine produced in the country due to a fall in the incidence of malaria and the appearance of a number of synthetic antimalarials and availability of imported quinine at a cheaper price. The Governments of Madras and Bengal are showing considerable hesitency in improving or expanding their plantations and factories, and are asking for a guarantee of off-take and prices of quinine produced in their factories, before undertaking any new developments. The Government of India, therefore, appointed a Special Cinchona Committee in 1951 to collect factual data regarding the existing conditions and assess the future prospects of these plantations. The Cinchona Committee have since submitted their report to the Government, and recommended that no new planting towards an actual expansion of the total area of cinchona should be undertaken. Even, while replanting areas normally vacated by uprooting of trees, they have recommended that the Governments should exercise a degree of caution for the next two years until the situation becomes clear. They have also recommended a detailed study of demands of quinine and synthetic antimalarials in different fields of consumption to assess the future markets for quinine.

6.5. *Madras plantations and Factories.*—The cinchona plantations and the quinine factories in the State are run by the Cinchona Department under the Ministry of Agriculture of the State Government, with a Director of Cinchona as head of the Department. The entire capital assets of the Cinchona Department amount to Rs. 1,82,00,000. The plantations are managed by two Superintendents, one stationed at Naduvattam for the Nilgiris, and the other at the Anamalai main plantations for the rest of them. The department engages 3,000 labourers per day on the plantations and factories. Two factories have been set up for extracting quinine from the cinchona bark, one at Naduvattam and another at Anamalai. The former has been in existence since 1871 and the latter is being installed.

6.5.1. *Naduvattam factory.*—The Naduvattam factory, which was started in 1871, is situated at Naduvattam in the Nilgiris, 20 miles from Ootacamund on the Ootacamund-Mysore Road. The capital investment on plant, machinery and building of this factory is estimated at Rs. 24,01,000. It employs 63 persons, out of whom 13 are technical personnel. From the cinchona bark, obtained from departmental plantations as well as from private plantations, quinine and other alkaloids are extracted, and different salts of quinine produced in the factory. It has a capacity of extracting annually 8,00,000 lbs. of cinchona bark, working one shift a day. Its capacity for the production of quinine depends on the alkaloid content of the bark. With bark containing 3 to 4 per cent of quinine normally obtained from the plantations, it can produce 30,000 lbs. of quinine and 15,000 lbs. of cinchona febrifuge. The quantities of chemicals required for

processing cinchona bark in this factory are given in the following table:—

TABLE NO. 11—THE QUANTITIES OF CHEMICALS REQUIRED FOR EXTRACTION OF QUININE FROM CINCHONA BARK AT THE NADUVATTAM FACTORY

Name of Chemicals	Quantity of chemicals required for extracting	
	8,00,000 lbs. of bark	100 lbs. of bark
Slaked lime . . . . .	80,000 lbs.	10 lbs.
Solvent Oil . . . . .	18,000 gals.	2.25 gals.
Caustic soda . . . . .	1,12,000 lbs.	14 lbs.
Sulphuric acid . . . . .	56,000 lbs.	7 lbs.
Soda Ash . . . . .	50,000 lbs.	6.25 lbs.
Activated carbon . . . . .	4,000 lbs.	0.5 lbs.

6.5.2. The following table shows the quantities of different products obtained in this factory during the last three years and their sale values:—

TABLE NO. 12—THE QUANTITIES OF DIFFERENT PRODUCTS OBTAINED AT THE QUININE FACTORY, NADUVATTAM AND THEIR SALE VALUES DURING 1950-51 TO 1952-53.

Name of the product	1950-51		1951-52		1952-53	
	Qty. produced Lbs.	Sale Value Rs.	Qty. produced Lbs.	Sale Value Rs.	Qty. produced Lbs.	Sale Value Rs.
1. Quinine Sulphate .	19,062	8,76,852	6,141	2,82,486	10,420	4,79,320
2. Quinine Sulphate tablets ..	..	..	2,970	1,12,860	4,115	1,56,370
3. Quinine Hydrochloride .	2,920	1,60,600	2,546	1,40,030	940	51,700
4. Quinine Bihydrochloride	2,388	1,49,250	594	37,125	..	..
5. Quinine Bisulphate .	1,878	83,571	734	32,663	..	..
6. Totaquina . . . . .	..	..	..	..	2,205	66,150
7. Totaquina tablets ..	..	..	..	..	2,258	63,224
8. Cinchona Febrifuge .	9,400	2,06,800	9,294	2,04,468	8,652	1,90,344

6.5.3. The Committee observed during their visit to the factory that the plant and equipment were old and antiquated and the methods adopted obsolete. As the State Government were not sure of the future of the Industry, no steps were taken to improve the factory, as it involved more capital investment. No reserves had been built to finance schemes of improvement or expansion, as the factory was worked on a "no-profit no-loss" basis and its selling price kept low, even when the prices in the market were high. The cost of production per pound of quinine in this factory during 1938-39 and 1950-51 as worked out by the Special Cinchona Committee is as follows:—

Item	1938-39 Rs.	1950-51 Rs.
Cost of bark in situ. . . . .	8.63	29.16
Harvesting charges . . . . .	0.88	4.44
Cost of extraction . . . . .	1.47	7.78
<b>TOTAL . . . . .</b>	<b>10.98</b>	<b>41.38</b>

The figures for 1938-39 are for bark containing 4.52 per cent of quinine, while for 1950-51 are for bark containing 2.5 per cent of quinine. The increase in cost of production has been attributed to the increase in wages and cost of materials in addition to the poor quality of bark treated. It will be seen that the major item in the break up of cost of production is the cost of bark, followed by the cost of extraction. The cost of bark mainly comprises of the direct recurring expenditure incurred on the plantations and would apparently remain almost the same for a unit weight of bark irrespective of its quinine content. If in the cost given for 1950-51, the bark used had a quinine content of 5 per cent. instead of 2.5 per cent., the amount of bark required per lb. of quinine would be exactly half bringing down the cost of production of quinine from Rs. 41.38 to Rs. 26.78. We were told that the bark worked in Java had a very much higher alkaloid content going up to 17 per cent and this accounted for the lower cost of production of quinine in Java. Planting of varieties of Cinchona yielding bark with a higher quinine content would therefore be a very effective way of bringing down the cost of production. We were told that a beginning had been made in this direction in the Naduvattam plantations and plants yielding bark with 16-17 per cent quinine content were being introduced. But at the present rate of replacement with these plants, a considerable time will elapse before bark of 16 to 17 per cent quinine content would be available in substantial quantities for extraction in the factory. We, therefore, recommend that the State Government should accelerate this scheme and bring about a rapid replacement of the existing cinchona plants, with those whose bark yield a higher quinine content.

6.5.4. The cost of extraction has also risen considerably from 1939 to 1951 due to the rise in the cost of chemicals used in the extraction. Several of these chemicals used in the process of extraction could be recovered and consumption of others reduced, if only the equipment at present employed in the factory is modernised and improved methods of extraction adopted. From a comparison of the figures of consumption of chemicals for extraction of quinine from a unit weight of bark at the quinine factories in Naduvattam and Mungpoo given in the Table Nos. 11 and 13 respectively, it will be seen that the rate of consumption of chemicals at the Naduvattam factory is very much higher. This is specially so in regard to solvent oil which could be recovered more efficiently with a modern recovery unit. This clearly indicates that there is considerable scope for improvement in the equipment used and methods adopted at this factory. The States Government should, therefore, take up actively the modernising of the extraction plant in addition to improving the plantations, if they want to bring down their cost of production to face the competition from imported quinine and synthetic anti-malarials.

6.5.5. *Anamalai Factory.*—A new factory is being installed at Anamalai with a capacity to produce 80,000 to 1,00,000 lbs. of quinine salts and 40,000 lbs. of cinchona febrifuge annually. A considerable amount of money appears to have been invested in the building and equipment of this factory. The Committee was informed that the plant had been designed by the previous Director of Cinchona and the fabrication and erection of the plant and construction of the factory building carried out by the State Public Works Department. Part of the equipment appears to have been fabricated locally and part purchased from outside. The Committee feel that the design of equipment and lay out of the factory leaves much scope for improvement. Electric power that is available on the plantations should be utilised to the fullest extent in mechanising the factory in all its departments. This will help to bring down considerably the cost of production.

6.5.6. Today in the chemical industry, there is no need to design a special set of equipment for the manufacture of each product. Chemical manufacturing procedure consists of a co-ordinated sequence of unit processes and operations that convert the raw materials into the finished product. These unit processes and unit operations are carried out in equipment of standard design of which a large variety are available. While designing a plant for the production of any chemical, one has only to choose, out of the different types of standard equipment available for each of these unit processes and operations involved. There are reputed chemical engineering firms in India today which not only suggest standard designs of equipment and their lay out for production of different chemicals, but also undertake their fabrication and instal them. The Committee feel that if the work of designing the plant, and drawing out a lay out for the quinine factory at Anamalai had been entrusted to any such experienced chemical engineering firm, a more compact and efficient unit could have been put up at a much lower cost. Even now, a re-arrangement of the existing equipment and mechanisation of certain operations now designed to be carried out

manually, would help in improving the efficiency of this factory. For instance, a simple mechanical device like a rotary mixer for mixing cinchona bark-powder with lime instead of the present arrangement to carry it out manually, will help to minimise labour costs and improve the overall efficiency. Any chemical engineering firm experienced in such work will be able to suggest the required alterations to the lay out of the factory and indicate suitable equipment for mechanising the operations where required. This work should be undertaken without delay. Quinine produced in the country is already facing severe competition from imported quinine and other antimalarials. Under the circumstances, the new factory at Anamalai should be made as efficient as possible, if production of quinine in this factory has to successfully withstand competition.

6.5.7. Sufficient attention has not been paid by the Madras Government for providing elementary amenities to the staff of the Cinchona Department stationed in the plantations. Though electric power is available on the plantations yet it is denied for lighting the quarters of the staff and for working the X-Ray plant in the hospital. The Committee feel that every amenity should be afforded to the staff especially as they are living in isolation without any social contacts.

6.6. *Bengal Plantations and Factory.*—The Cinchona Plantations and the Quinine Factory are run by the Cinchona Department, which is at present under the Ministry of Commerce and Industries, Bengal Government. The Cinchona Department has a Director of Cinchona as its head and comprises of four sections:—

- (a) The Cinchona Plantations.
- (b) The Quinine Factory.
- (c) The Research Branch.
- (d) The Quinine Sale Depot.

The four Cinchona plantations located at Mungpoo, Munsong, Rango and Latpanchor are under the overall supervision of a General Manager under whom are four Managers in charge of each of these plantations. These plantations are further sub-divided into divisions and are under Divisional Officers. The Plantations engage about 5,400 labourers per day. The capital investment on the entire plantations is estimated at about Rs. 42,00,000.

6.6.1. The Mungpoo factory which was started in 1895 for extracting quinine from the bark obtained from the plantations is situated at Mungpoo at a distance of about 40 miles from Siliguri. The capital investment on the plant, machinery and buildings of this factory is estimated at about Rs. 3,00,000. The factory is under the charge of a Quinologist, who is assisted by 3 Assistant Quinologists. It employs 140 labourers and has a capacity of extracting 21,00,000 lbs. of cinchona bark per annum, working one shift a day. With bark containing on an average 4 per cent of quinine that is being harvested, at present, it can produce 70,000 lbs. of quinine and 35,000 lbs. of cinchona febrifuge per annum. The quantities of chemicals required for extracting quinine from cinchona bark at this factory are given in the following table:—

TABLE NO. 13—THE QUANTITIES OF CHEMICALS REQUIRED FOR EXTRACTION OF QUININE FROM CINCHONA BARK AT THE MUNGPPOO FACTORY

Name of Chemicals	Quantity of chemicals required for extracting	
	21,00,000 lbs of bark	100 lbs of bark
Solvent oil . . . . .	25,000 gals.	1·2 gal.
Caustic soda (98-99%) . . . . .	3,13,600 lbs.	14·9 lbs.
Sulphuric acid (98%) . . . . .	1,00,800 lbs.	5 lbs.

6.6.2. The following table shows the quantities of different products obtained in this factory during the last three years and their sale values:—



सत्यमेव जयते

TABLE NO. 14—THE QUANTITIES OF DIFFERENT PRODUCTS OBTAINED AT THE MUNGPOO FACTORY AND THEIR SALE VALUES DURING 1950-51 TO 1952-53

Name of the product	1950-51		1951-52		1952-53		Remarks
	Qty. in lbs.	Sale value in Rs.	Qty. in lbs.	Sale value in Rs.	Qty. in lbs.	Sale value in Rs.	
I. Manufacture from Bark :							
1. Quinine Sulphate Powder ..	55,515	23,87,145	47,182	24,06,282	48,248	22,67,656	B.P. 1948.
2. Cinchona Febrifuge Powder .	2,520	50,400	4,501	90,020	18,164	3,63,280	I.P.L. 1946.
II. Manufacture from Quinine Sulphate and Cinchona Febrifuge Powder :							
1. Quinine Hydrochlor (Powder)	10,757	5,48,607	4,329	2,29,437	7,111	3,76,883	B.P. 1948.
2. Quinine Bihydrochlor (Powder)	2,515	1,34,552	2,435	1,33,925	1,710	94,050	Do.
3. Quinine Bisulphate (Powder)	363	15,609	194	8,342	765	32,885	Do.
4. Quinine Hydrobromide (Powder)	18	918	..	..	7	371	B.P.C. 1949
5. Quinine Bihydrobromide (Powder)	2	102	3	116	1	58	B.P.C 1934
6. Quinine Salicylate (Powder)	1	51	..	162	1	54	B.P.C 1949
7. Quinine Tannate (Powder)	..	..	..	..	7	168	B.P.C. 1949
8. Totaquina (Powder)	..	..	4,800	1,32,000	4,541	1,24,877	B.P. 1948
9. Quinidine Sulphate (Powder)	..	..	..	..	16	720	B.P. 1948
10. Cinchonine hydrochlor (Powder)	..	..	..	..	1	29	B.P.C. 1934
11. Quinine Sulphate (Tablet).	4,004	2,55,204	3,645	1,82,250	4,295	2,14,650	
12. Quinine Hydrochloride "	57	2,907	..	..	43	2,365	
13. Quinine Bihydrochlor "	162	8,586	207	12,006	..	..	
14. Quinine Bisulph "	116	5,220	157	7,065	119	5,355	
15. Quinine Bihydrobrom "	..	..	2	122	..	..	
16. Quinine Hydrobromide "	..	..	..	..	1	55	
17. Quinine Tannate "	..	..	..	..	3	75	

6.6.3. The Committee observed during their visit to the factory that, although the plant and equipment were old, the factory was neatly designed and is being maintained in very good condition. Its source of power is a water-wheel worked by a perennial mountain rivulet flowing down the slopes of the Mungpoo hill. All the machinery draw their power from a main shaft which is rotated by this water-wheel. Enough electric power for lighting and other purposes is also generated by a dynamo connected to the main shaft. Steam generated by two boilers is used for evaporating and heating. Except for the transport of the mixture of lime and cinchona bark powder to the extraction tanks which is being carried out manually in buckets, all the other unit operations like mixing, stirring etc., are being carried out mechanically. The Committee recommend that this operation should also be mechanised to improve the efficiency of the factory. A moderately equipped workshop has been provided for maintenance work of the factory.

6.6.4. The cost of production per lb. of quinine in this factory during 1938-39 and 1950-51 as worked out by the Special Cinchona Committee is as follows:—

Item	1938-39	1950-51
Cost of bark in Situ	5.25	24.00
Harvesting charges	0.93	3.43
Cost of extraction	1.53	7.93
<b>TOTAL</b>	<b>7.77</b>	<b>35.36</b>

Here also, it will be seen that there is a considerable increase in the cost of production, which can be attributed to increase in wages and cost of raw materials. This cost of production could be brought down considerably by improving the quinine content of the bark. Steps have been taken in this direction and in the plantation at Latpanchor, they have been able to reach upto 16 per cent of quinine content in the bark. We recommend in this case also that the State Government should accelerate the scheme of replacement of the existing cinchona plants with those yielding bark with a higher quinine content.

6.7. *Assam Plantations.*—During 1941, large scale experimental plantations were started by the Assam Government at Nongpoh and Umsaw in the Khasi Hills. This was as a result of the recommendations of the Provincial Malaria Committee, and trials made on a small scale in the past having indicated possibilities of its cultivation in these hills in the State. These plantations, which had extended to about 19 acres by 1943-44, were progressively expanded and at present extend over about 800 acres. The capital investment so far on these plantations has been estimated at Rs. 13.5 lakhs. It is reported that the bark on the average contains 3 per cent quinine and the yield of bark per acre is 1330 lbs., which works out approximately to about 40 lbs. of quinine per acre. The State Government have a programme to extend these plantations to 1,000 acres by 1954-55 at an



additional cost of Rs. 1½ lakhs. By cleaning 100 acres every year and working the bark for quinine it is estimated that they will be able to meet the States' requirements of about 5,000 lbs. of quinine per annum. A scheme for putting up a plant for the extraction of quinine and other alkaloids at an estimated cost of Rs. 5 lakhs has been included by the State Government in their five year development plan. The site for the location of the factory has, however, not yet been finalised.

6.7.1. We visited these plantations during our itinerary in Assam. Even the plants which were 8 to 10 years old, had a very small girth, and consequently very little bark on them, which could be used for the extraction of quinine. The poor condition of the plants was attributed by the Forest Department to their lack of experience in looking after the cinchona plantations, and also to the unsuitability of the altitude and soil, in which they had been planted. We were also informed that more suitable areas in the Khasi Hills were not under their control and, therefore, could not be utilised for the purpose. We do not consider that the setting up of a factory for working the bark from these plantations for a small production of 5,000 lbs. per annum is worth the while. There is enough production of quinine in the country, and even with better plantations, the Bengal and Madras Governments are finding it difficult to compete with the existing prices of quinine in the country. Extraction of quinine from the plantations at Assam, we consider, under the circumstances, would be most uneconomical. From what we have seen of the plantations in Assam, we consider that the place is also not very suitable for cinchona, and it will not be advisable to extend these plantations specially when the Special Cinchona Committee have advised against any expansion of the existing plantations in the country. Since the Assam Government have spent a considerable sum of money on these plantations, and would like to get some return they should examine the possibility of having the quinine extracted out of their bark in the factory of the Bengal Government at Mungpoo which has, at present, a surplus capacity. This will also enable the State to study the economics of working the bark from the plantations, and enable them to decide, if any new planting to replace those that are removed would be worth the while. When the country is short of a number of other medicinal plants and Assam is endowed with all the natural advantages for their cultivation, the State should concentrate more on them rather than fritter away their finances and energies on extending the cinchona plantations and setting up a new factory for the extraction of quinine, when there is already a surplus production of quinine in the country.

6.8. *Assistance to Quinine Factories.*—The quinine factories of both the States of Madras and Bengal have complained of a poor offtake of their production and of accumulation of unsold stocks in their factories. Several causes have contributed to this fall in the offtake of quinine. The first and foremost is the rapid fall in the incidence of malaria as a result of the antimalarial campaigns undertaken by Governments by spraying D.D.T. and other insecticides on an extensive scale. With the partition of the country, the highly malarious areas of East Bengal have gone over to Pakistan. Immediately after Partition, exports of quinine outside the country were banned for

some time. By the time this ban on export was actually lifted, East Pakistan had started importing quinine from other countries and was not willing to take quinine from India. Till the beginning of 1953, imports of quinine into the country were being liberally permitted and allowed to be sold without any restriction, while on the other hand for some period, a control was exercised on the distribution of quinine produced in the country. Due to the various formalities, one had to undergo for obtaining supplies of indigenous quinine because of this control, the consumers started naturally utilising more and more of the imported variety on which there was no control. Even after the lifting of control on the quinine produced in the country, the lack of commercial methods of marketing in the Government quinine factories came in the way of improving their offtake.

6.8.1. The imports of quinine into the country have been restricted from the beginning of 1953. But this does not seem to have had any appreciable effect in reducing its imports, as will be seen from the following table showing imports of quinine during different months for the years 1951-53:—

TABLE NO. 15.—THE IMPORTS OF QUININE DURING DIFFERENT MONTHS FOR THE YEARS 1951-53

Month	Quantity in lbs. imported during		
	1951	1952	1953
January	Nil	7,971	18,646
February	Nil	3,457	3,340
March	Nil	4,764	4,240
April	31	13,528	6,479
May	2,130		10,685
June	1,056		3,277
July	3,610	1,726	3,238
August	4,144	3,919	357
September	8,133	5,503	7,799
October	3,765	3,970	3,673
November	1,815	9,567	1,834
December	3,234	7,836	..
TOTAL	27,918	62,241	63,568
Monthly average	2,326	5,187	5,297

Since the import licences specify only the value of the quinine and not the quantity, it is reported that people take advantage of it and import large quantities for the amounts allotted in the licence by declaring ridiculously low prices. This needs careful investigation.

6.8.2. The imports of quinine, at present, are mostly from Japan at prices, at which the Indian made quinine cannot compete. These exports from Japan are reported to be from accumulated stocks in that country and owe their origin to Java which was under Japanese occupation during the war. The price, at which this quinine and its salts are made available, has therefore no relation to its actual cost of production in Java. The present condition of cinchona plantations at Java is also reported to be not in a position to supply large quantities to other countries for several years to come. Therefore, once the accumulated stocks of quinine in Japan are exhausted, no further supplies of quinine from Java are likely to replace them for some time. It is, therefore, necessary to protect the indigenous quinine industry, which has been developed after many years of effort, and considerable expenditure, and prevent the dumping of foreign quinine into the country.

6.8.3. The import of large quantities of synthetic antimalarials has also adversely affected the industry. In spite of several developments that have taken place in the sphere of the synthetic drugs, in many instances, the use of quinine has been preferred in the treatment of malaria. The use of quinine has, therefore, not yet become obsolete and it is likely to hold its place in medicine for many more years to come. Taking these aspects into consideration, the Committee recommend that imports of quinine and synthetic antimalarials should be effectively restricted and a customs duty should be levied on their imports. As there is no shortage of quinine in the country, such a step will not adversely affect the interests of the consumers but will increase the offtake of the accumulated stocks of quinine, at the same time, helping to conserve the industry which has been of great service, specially in emergencies, and has reduced the dependence of this country on foreign supplies.

6.8.4. In the quinine factories of Madras and Bengal States, large stocks of cinchona febrifuge obtained during the manufacture of quinine have accumulated for lack of a demand for them. Although, the Malaria Chemo-Therapy Committee have recommended that this product should be used extensively by all Government and private institutions in the country, the response has been very poor. We have been approached for help by these factories in the matter of disposal of these accumulated stocks. It is suggested that it should be made incumbent on all Government and local-fund institutions to purchase a fair percentage of their requirements of antimalarials in the form of cinchona febrifuge or that cinchona febrifuge alone should be used for free distribution wherever there is need for such a distribution of antimalarials. Although we consider that any compulsion in the matter would not be practicable, we strongly recommend that the State Government, District and Local Boards and other bodies should be requested to use this product to meet a part of their requirements of antimalarials and a general appeal in this connection should be sent to these bodies.

## **7. Shark Liver Oil Factories:**

7.1. During World War II, the main source of cod liver oil was cut off due to the German occupation of Norway. It became increasingly difficult to meet the huge demand of the defence forces for

vitamin 'A' oils and the civilian requirements for the treatment of vitamin 'A' deficiency. Attention was, therefore, paid to the development of its sources within the country and preliminary investigations undertaken in this connection revealed that shark liver oil containing a high vitamin 'A' concentration could be extracted on a commercial scale and used for medicinal purposes. Factories for its extraction were, therefore, put up by the States of Madras and Bombay.

7.2. *Bombay Factory*.—The Bombay factory, which is situated at Saseon Docks, is managed by the Fisheries Technological Laboratory of the Fisheries Department of Bombay Government. The Fisheries Department is entrusted with investigations on problems relating to ancillary industries like Shark liver oil, gelatine, glue, fish-meal etc. The capital investment on this factory is about Rs. 2,10,000. It employs 3 technical personnel and 11 labourers and has been in production since 1946. Shark Liver, which is purchased from fishermen, who catch sharks mostly during the period from October to December and again in April and May, forms the starting material. The oil from the shark liver is extracted in a steam-heated fish-liver boiler under vacuum. The extracted oil is subjected to further refining by cooling the oil below 0°C. when the stearine solidifies and is removed by filtering. A special super-centrifuge is used to obtain a clear sparkling product. In addition to the refining of oil extracted from liver, at the factory, shark liver oil extracted by fishermen themselves, by a simple process demonstrated to them by this laboratory, is also purchased and refined.

7.3. The different grades marketed by the factory comprise of:—

- (i) "Sharkovit" with a vitamin A and D content of 1,000 and 100 I.U. per gm. respectively;
- (ii) "Elasmin Liquid" which is concentrated with vitamin A and D content of 20,000 and 2,000 I.U. per gm. respectively;
- (iii) Neat shark liver oil with a vitamin A content of 10,000 I.U. per gm.; and
- (iv) The veterinary grade shark liver oil with vitamin A and D content of 5,000 and 500 I.U. per gm. respectively.

To overcome the characteristic odour of fish liver oils, which is a drawback in its popularity with the consuming public, the laboratory produces '3 minim pearls' containing 3,000 I.U. of vitamin A and 300 I.U. of vitamin D per pearl. An encapsulation unit has been put up for the purpose at a cost of Rs. 25,000. A bigger encapsulation unit, it is understood, has been ordered out from America and will be soon installed at this laboratory for the manufacture of these capsules in larger quantities and at a cheaper cost. In the manufacture of the different products, groundnut oil is used as a diluent and synthetic vitamin 'D' (calciferol) used for making up its concentration as the shark liver oil is not particularly rich in this vitamin. The following table gives the quantity and value of the various products sold during the last three years:—

TABLE NO. 16—THE QUANTITIES AND SALE VALUES OF VARIOUS PRODUCTS MADE AT  
THE BOMBAY GOVERNMENT SHARK LIVER OIL FACTORY, BOMBAY

	1950-51		1951-52		1952-53	
	Quantity	Value Rs.	Quantity	Value Rs.	Quantity	Value Rs.
<b>(i) Shark Liver Oil Bombay Brand :</b>						
Gallons	4,794	55,067	5,598	78,141	12,792	1,65,073
10 oz.	3,204	5,674	6,212	9,530	9,791	12,848
16 oz.	.	.	..	.	10,254	17,204
<b>(ii) Elasmín Liquid :</b>						
1 oz.	6,721	9,241	6,819	9,606	4,921	7,306
16 oz.	40	360	772	7,282	303	3,450
Gallons	66	5,030	4	320	33	2,768
<b>(iii) Neat Shark Liver Oil :</b>						
Gallons	2,314	50,628	2,422	37,109	1,489	29,800
<b>(iv) Veterinary Grade Shark Liver Oil :</b>						
Gallons	21	420	59	1,180	166	3,320
<b>(v) Elasmín Pearls :</b>						
50 Pearls	14,624	29,248	20,158	40,308	18,825	35,700
1000 Pearls	197	8,910	630	19,598	834	22,500
Loose Pearls	1,10,000	2,475	..	.	..	..

7.4. The factory has also a well-equipped control laboratory set up at a cost of Rs. 30,000 to test samples of shark liver oil. In this laboratory, samples of shark liver oil produced by other manufacturers are also tested for their vitamin 'A' content. The products of this factory are supplied to the public through M/s. Kemp & Co., Bombay who have branches in Madras, Delhi and Calcutta. M/s. Kemp & Co., who obtain the products from the factory at fixed prices supply it to the dealers, medical profession or consumers at prices fixed by the Bombay Government for such supplies within and outside the State of Bombay. The supplies to Government and other medical institutions are made directly by the factory at the same prices as are fixed for the supply to the distributors by the Government.

7.4.1. It must, however, be pointed out that the selling prices fixed by the Government give a greater margin of profit to the Distributor than to the Retailer. Normally, it should be the reverse considering the character of the Distributor being mainly wholesale and as such he has a greater turnover than the Retailer in a given time. For instance each bottle of shark liver oil (10 fluid ozs.) is sold by the factory to the Distributor at Rs. 1-5-0 to be sold by him for Rs. 1-8-0 to the Dealer in Bombay who sells it to the customer at Rs. 1-10-0. Thus on each bottle sold, the wholesaler makes 3 annas as against 2 annas made by the Retailer. The profit margins should, therefore, be rationalised.

7.5. *Madras Factory.*—The manufacture of shark liver oil, which was carried out on an experimental scale at the Fisheries Experimental Station, Tanur, was taken up on a commercial scale in 1940, by the Kerala Soap Institute, Kozhikode, which is run by the Industries Department of the State Government. In 1952, this was separated from the Soap Factory and a factory at a new premises was set up for the manufacture of shark liver oil with a capital cost of about Rs. 3,16,000. The factory employs 2 technical personnel and 43 labourers. The starting raw material is shark liver oil which is purchased from the fishermen.

The products made by the factory comprise of:

- (i) MGB Shark Liver Oil and Stayfit Brand Shark Liver Oil with Vitamin A & D content of 1,000 and 100 I.U. per gm. respectively;
- (ii) Adamin oil with a vitamin A & D content of 12,000 and 1,000 I.U. per gm. respectively;
- (iii) two grades of pure shark liver oil each guaranteed to contain 6,000 and 20,000 I.U. per gm. of Vitamin A; and
- (iv) 3 minim capsules containing 4,000 and 1,000 I.U. of vitamin A & D respectively per capsule.

The factory, however, has no encapsulation unit but gets it done from a concern in U.K. to whom the oil is shipped. Here again groundnut oil is used as a diluent and synthetic vitamin D<sub>2</sub> (calciferol) added to make up its concentration. The following table shows

the actual quantity of the different grades of shark liver oil made and raw materials consumed during the last three years:—

TABLE NO. 17—THE PRODUCTION OF DIFFERENT GRADES OF SHARK LIVER OIL AND RAW MATERIALS CONSUMED AT THE KOZHIKODE FACTORY

Products made	1949-50		1950-51		1951-52	
	Qty (glns.)	Sale value (Rs.)	Qty (glns.)	Sale value (Rs.)	Qty (glns.)	Sale value (Rs.)
MGB Oil	13,500	2,43,000	9,700	1,74,600	12,850	2,29,500
S TAYFIT Oil	250	4,000	2,150	34,400	3,000	48,000
Adamin oil	121	30,250	98	24,500	88	22,000
<i>Raw Materials Consumed</i>						
Shark Liver Oil	1,02,000 lbs.	..	34,100 lbs.	..	36,450 lbs.	..
Groundnut Oil	38½ tons	..	36½ tons	..	54½ tons	..

7.6. The products of this factory are distributed through agents and representatives appointed at Madras, Bombay, Nagpur, Calcutta, Dibrugarh and Delhi, who get a commission varying from 6½ to 10 per cent. on the value of the products. In addition, the dealers are given a discount varying from 15 to 25 per cent. Supplies in bulk packings, on which no discounts are allowed, are made only to Government institutions, hospitals, dispensaries and charitable institutions.

7.7. The products of these factories compare favourably with the imported cod liver oil both in their physical characteristics and vitamin content. The nauseating odour of this oil, which was noticed, when it was first put in the market, and which made it very unpopular among the consuming public, has now been practically eliminated. Both the factories are trying to improve their products still further.

7.8. In view of the extreme importance of vitamin 'A' in the nutrition of the people, the lack of which has been responsible for extensive ill-health in the country, it may be necessary to supply it as a routine measure particularly to the vulnerable age-groups of the population. The Panel on Fine Chemicals, Drugs and Pharmaceuticals appointed by the Government of India in 1945-46, therefore, stressed the need for putting the industry on a sound and permanent footing and suggested the formation of a permanent Advisory Board whose functions should be (i) to indicate steps for securing adequate supplies of sharks; (ii) to study and fix seasons, during which fishing should be carried out to safeguard the proper breeding of sharks; (iii) to devise proper methods for the extraction of shark liver oil and utilisation of by-products; and (iv) suggest other measures for improving the industry. No attempts have been made to implement this suggestion made by the Panel, while on the other hand, the two Government factories are competing with each other for the sale of

their products, and trying to obtain the raw material at as cheap a price as possible from the local fishermen, to whom has been entrusted the job of catching the sharks. By this unregulated fishing adopted at present, a very valuable source of vitamin 'A' might be lost to the country. The Central Government should, therefore, look into this matter urgently and see that necessary steps are taken for conserving this important source and bring about a better co-ordination in its exploitation by the two State Governments.

7.9. There is also a lack of co-ordination between the manufacturing and marketing activities of the two Government factories. A uniform size of packing and quality with a common brand instead of calling them differently as 'Madras Government Shark Liver Oil' and 'Bombay Government Shark Liver Oil' should be adopted by the two factories. They should also adopt uniform selling prices for different grades, scales of discount to traders and have a common publicity for the products made. If necessary, the territories where they should market their products can be distributed between the two factories. After all, these two State Governments have undertaken the production of this essential commodity at a time when, for lack of its production within the country, a great shortage was felt. Even now they are playing an important part in making the country independent of foreign supplies of this essential commodity.

#### **8. Other Government Institutions:**

8.1. During the end of the last century and early part of this century, several medical research institutions, which had been started by Government took on the work of producing vaccine and sera in addition to undertaking clinico-pathological research work. As the possibility of prophylaxis against bacterial infections improved, these institutions have augmented their activities and new ones have come into existence. The following table shows the names of such institutes and their capacity and actual production of vaccines, sera and antitoxins:—



TABLE No. 18—THE CAPACITY AND PRODUCTION IN 1952 OF VACCINES, SERA AND ANTITOXINS  
IN GOVERNMENT INSTITUTIONS IN INDIA

S. No.	Name of the Institution	VACCINES					SERUM	
		T.A.B. Vaccine in ccs.	Cholera Vaccine in ccs.	Antirabic Vaccine in ccs.	Plague Vaccine in ccs.	Lymph Vaccine (small-pox) in doses.	Anti-venine in ccs.	Other Serum in ccs.
1	2	3	4	5	6	7	8	9
		<i>(Annual capacity for production)</i>						
1.	Central Research Institute, Kasauli	20,00,000 (9,34,700)	40,00,000 (17,15,700)	52,00,000 (47,11,400)	..	..	1,50,000 (1,37,400)	20,000 (8,600)
2.	Haffkine Institute, Bombay	10,00,000 (2,71,000)	2,00,00,000 (45,84,000)	26,00,000 (23,39,700)	3,00,00,000 (49,45,000)	..	8,200 amples. (7,100) amples	9,60,000 (8,37,700)
3.	Pasteur Institute, Shillong	1,00,000 (92,000)	10,00,000 (6,88,500)	3,50,000 (3,24,300)	..	..	..	..
4.	Provincial Hygiene Institute, Lucknow (U.P.)	..	30,78,000 (30,00,000)	..	..	..	..	..
5.	Vaccine Institute, Belgaum	..	..	..	..	47,96,100 (47,96,100)	..	..
6.	Vaccine Depot, Shillong	..	..	..	..	30,00,000 (24,83,100)	..	..
7.	Government Vaccine Depot, U.P.	..	..	..	..	1,25,00,000 (77,10,900)	..	..
8.	M.P. Institute, Nagpur	..	..	..	..	28,22,600 (25,46,600)	..	..
9.	Public Health Lab., Travancore-Cochin	12,00,000 (50,000)	10,00,000 (2,50,000)	10,00,000 (6,64,400)	..	73,500 c.c. (64,200) c.c.	..	..

I	2	3	4	5	6	7	8	9
10. Vaccine Institute, Bangalore	..	..	..	..	..	1,00,00,000 (20,00,000)	..	..
11. Vaccine Institute and Vaccine Laboratory, Calcutta	..	..	35,00,000 (34,97,000)	..	..	2,41,000 c.c. (2,00,000) c.c.	..	..
12. King Institute, Guindy	..	1,86,500 (1,86,500)	1,09,37,500 (1,09,37,500)	..	..	60,38,200 (60,38,200)	..	..
13. Vaccine Institute, Namkum. (Bihar)	..	..	..	..	..	1,20,00,000 (1,20,00,000)	..	..
14. Public Health Central Laboratory, Hyderabad	..	..	20,00,000 (20,00,000)	..	..	21,30,000 (21,30,000)	..	..
15. Public Health Institute, Bangalore	..	29,000 (29,000)	14,52,000 (14,52,000)	..	1,24,000 (1,24,000)	..	..	..
16. Lymph Depot, Gwalior	..	..	..	..	..	10 lbs. (10 lbs)	..	..
17. Pasteur Institute, Coonoor	..	..	..	35,00,000 (35,00,000)	..	..	..	..
18. Drug Research Laboratory, Jammu	..	20,000 (20,000)	20,000 (20,000)	..	..	..	..	..
TOTAL	..	45,35,500 (15,83,200)	4,69,87,500 (2,81,44,700)	1,26,50,000 (1,15,39,800)	3,01,84,000 (50,69,000)	5,32,87,200 (3,97,04,700) 3,14,500 c.c. (2,64,500) c.c. 10 lbs. (10 lbs.)	1,50,000 (1,37,430) 8,200 ampis. (7,100)	9,80,000 (8,46,280)

NOTE—The figures in brackets indicate the actual production in 1952.

8.2. *Antirabic Vaccine and Serum.*—The antirabic vaccine for the treatment of rabies was produced for the first time in 1900 by the Central Research Institute, Kasauli. Since then, its production has been taken up in other institutes like the Haffkine Institute, Bombay, Pasteur Institutes at Shillong, Coonoor, and Calcutta and Public Health Laboratory, Travancore-Cochin. The total capacity for producing antirabic vaccine at these institutes is 1,26,50,000 c.c., the actual production during 1952 being 1,15,40,000 c.c. In addition, the Haffkine Institute, Bombay is carrying out experiments for the production of hyperimmune rabies serum. This serum is not manufactured in India at present and rabid dog bite cases are only treated with antirabic vaccine, the efficacy of which is not guaranteed in every case. It is reported that treatment with hyperimmune rabies serum followed by antirabic vaccine gives almost cent. per cent. success. The production of hyperimmune rabies serum in institutes like the Haffkine Institute where facilities for its production exist should be taken up in adequate quantities to meet the needs of the country. Because of the very essential nature of the product all schemes for its production should be actively assisted both by the State and Central Governments. The Haffkine Institute possesses, in addition, facilities for the production of the avianised rabies vaccine required for the protection of dogs against rabies. Compulsory immunising of all pet dogs against rabies by periodical vaccination coupled with the destruction of stray dogs will bring down the incidence of rabies in the country to a negligible amount. It is, therefore, very essential to increase its production and make it more easily available for eradicating the danger of rabies in the country.

8.3. *Vaccine Lymph.*—Vaccine lymph is manufactured by many of the Government institutes. The total capacity for its production is 5,32,87,200 doses, the actual production in 1952 being about 3,97,04,700 doses. It is reported that the Vaccine Institute, Bangalore, has successfully worked out a method for the bacterial purification of calf lymph without affecting the potency of the lymph. It may be worthwhile for other institutes to examine the possibility of adopting this method and producing the improved type of this vaccine for prophylaxis throughout the country.

8.4. *Whooping Cough, Diphtheria and Tetanus Vaccines.*—Whooping cough vaccine is at present mainly imported and the other two vaccines are not being produced in adequate quantities in the country. In almost all the advanced countries, children are being protected against tetanus, diphtheria, and whooping cough by the simultaneous use of the three vaccines as these diseases otherwise take a heavy toll of children specially of the school going age. For adopting a similar step in this country, it will be necessary to undertake the manufacture of whooping cough vaccine in large quantities and also increase the output of diphtheria and tetanus vaccines. The Haffkine Institute, Bombay has carried out experiments on the production of whooping cough vaccine and the scheme for its production should be actively encouraged. An attempt should be made to produce the triple vaccine.

8.5. *Influenza Vaccine.*—With the experience gained during the influenza epidemic after World War I, when for want of prophylactic,

and therapeutic drugs, a heavy toll was taken by this disease throughout the world, it is necessary to keep production of this vaccine ready at hand to meet such eventualities. We understand that the Haffkine Institute has carried out experiments for the production of this vaccine and has been nominated as one of the centres under the World Health Organisation Programme for its production to meet any emergency. Investigations on its production should be actively encouraged and the production of the right type of vaccine to meet the emergency should be undertaken at this institute.

8.6. *Antitoxins and Sera.*—Until the end of World War I, India depended entirely on foreign imports for the supply of antitoxins and sera. The first attempt to produce them was made in 1919, but until the beginning of the Second World War, large quantities of their imports were being received into the country. In 1940, the Government organised production of antitoxins and sera in laboratories like the Haffkine Institute, Bombay and the Central Research Institute, Kasauli, with the object of making the country independent of foreign imports, and set standards for such products in the country. The present capacity for the production of sera and antitoxins of private and Government institutions is 19,58,500 c.c., the production in 1952 being 16,20,900 c.c. There is no doubt that the demand for sera and antitoxins will increase rapidly as medical facilities within the country improve. Special efforts will have to be made to produce them in larger quantities.

8.6.1. A special mention in this connection may be made of the antivenine serum which is an antidote against bites of poisonous snakes. This is being produced by the Haffkine Institute, Bombay and the Central Research Institute, Kasauli. The Haffkine Institute which has taken a lead in its manufacture make a polyvalent variety, which is effective against several poisonous snakes like Cobra, Russell's viper, Krait and Saw-scaled viper; while the Kasauli Institute only makes a divalent variety, which is effective against bites of Cobra and Russell's viper. The Haffkine Institute maintains a snake farm for obtaining the venom of the different species of snakes required for producing this serum, which is also supplied to the Kasauli Institute. The antivenine serum made at the Haffkine Institute is supplied in a lyophilised form and is reported to retain its potency for long periods upto 10 years even when stored at ordinary temperatures. Unfortunately, the availability of this serum is restricted, and hence it is not easily available in emergencies. The Government should, therefore, increase its production by affording facilities for the Haffkine Institute to expand its snake farm and by other institutes taking up its production. This serum should be made more easily available to the public by allowing it to be purchased and stocked by Chemists and Druggists. The lyophilised form of antivenine produced by the Haffkine Institute is specially suitable for stocking by the retail traders in drugs in out of the way places.

8.6.2. At present, the vaccines and sera made by the Government institutions are only available to Government hospitals. This practice should be revised and the products made available to the general public through retail trade. Commercial methods of marketing should be adopted in all cases.

8.7. *Synthetic Drugs*.—The manufacture of sulphathiazole has been undertaken by the Haffkine Institute, Bombay on a semi-commercial scale since 1948, starting from Acetanilide, Chlorosulphonic acid, Vinyl acetate and Thiourea based on a process developed and patented by the Institute. Since then, the Institute has been producing it in increasing quantities as will be seen from the following table:—

TABLE No. 19—THE PRODUCTION OF SULPHATHIAZOLE DURING 1948 TO 1953 AT THE HAFFKINE INSTITUTE, BOMBAY

Period	Quantity manufactured (in lbs)
1948 . . . . .	125
1949 . . . . .	1572
1950 . . . . .	1748
1951 . . . . .	2388
1952 . . . . .	4860
1953 (Jan.—March)	1341

The prices of sulphathiazole and other sulpha drugs which had rocketed high by the end of the last War were brought down considerably when the Institute started the production of this drug. The Institute has finalised schemes for the production of other sulpha drugs and synthetic antimalarials and concluded an agreement with M/s. Imperial Chemical Industries for the production of Proguanil Hydrochloride (Paludrine). But it has been handicapped in the furtherance of all its development programmes for want of proper supervisory staff for this work. The management of the Institute feels that this activity is not in keeping with its other functions and would be willing to hand it over to any Government organisation better suited for its supervision and management. The Committee have already suggested, while dealing with the Government Penicillin Factory at Pimpri, that the manufacture of synthetic drugs should be undertaken at this factory in addition to the manufacture of antibiotics. The possibility of transferring the present activity of manufacture of sulphathiazole of the Haffkine Institute and its schemes for the production of other synthetic drugs to the Government Penicillin Factory at Pimpri should, therefore, be examined. If this is not feasible, this section should be separated from the control of the Institute and the Bombay State Government asked to set up a separate organisation for the furtherance of this effort. As the Government have participated in the manufacture of this essential product and helped at a time when its supply was scarce in the country to stabilise the prices, the Committee feel that this activity should not be closed down.

**(ii) LARGE SCALE PRIVATE ENTERPRISE UNDER FOREIGN CONTROL  
AND/OR COLLABORATION:**

**1. Foreign Control:**

1.1. Firms run under foreign control in the pharmaceutical industry comprise of branches of foreign firms within this country and Indian subsidiaries of foreign firms. Some of these concerns are engaged mainly on imports, while others have, in addition, manufacturing activities. Among the latter, some have set up their own manufacturing departments, while others depend on the manufacturing departments of other firms. There are also firms in this category, which mainly process products for other firms and have little or no manufacturing activities relating to their own products. In most of the cases, the products are made under agreements with their principals or other foreign firms. We have discussed, at a later stage, the various aspects arising out of these agreements concluded by these firms.

1.2. The investments of foreign capital in industry have been welcomed by government and the following assurances given to them for encouraging such investments:—

- (i) There will be no discrimination between foreign and Indian undertaking in the application of general Industrial Policy;
- (ii) Reasonable facilities will be given for the remittance of profits and repatriation of capital consistent with the foreign exchange position of the country; and
- (iii) In the event of nationalisation, fair and equitable compensation would be paid.

The Planning Commission have also mentioned that in view of the fact that investment of foreign capital necessitates the utilisation of indigenous resources, and also that the best use of foreign capital acts as a catalytic agent for drawing forth larger resources for domestic investment, it is desirable that such investments should be channelled into fields of high priority. The broad principle to be followed, as laid out by the Commission, is that foreign investment should be permitted in as far as new lines of production are to be developed, or where special types of experience and technical skill are required, or where the volume of domestic production is small in relation to demand, and there is no reasonable expectation that the indigenous industry can expand at a sufficiently rapid pace. It will be worthwhile examining how far the firms with foreign investments in the pharmaceutical industry fulfil these stipulations.

1.3. The following table shows the capital investment, sale value of finished products made, and value of raw materials consumed, labour employed and nature of products undertaken by firms under foreign control:—

TABLE No. 20—THE CAPITAL INVESTMENT, SALE VALUE OF FINISHED PRODUCTS, VALUE OF RAW MATERIALS CONSUMED, LABOUR EMPLOYED AND NATURE OF PRODUCTS MADE BY THE FIRMS UNDER FOREIGN CONTROL.

Type of firms	Total No. of firms	Total capital invested Rs.	Value of finished products in 1952 Rs.	Value of raw materials consumed in 1952		Labour employed		Expenditure on advertisement in 1952		% of total sales (average)
				Indigenous Rs.	Imported Rs.	Technical	Non-Technical	Total Rs.	Total Rs.	
I. Firms with manufacturing departments :										
	19*	5,47,48,990	10,74,43,300 (61,35,950 being of cosmetics)	52,31,550	3,78,85,750	346	3,083	3,429	74,98,430	9.07
II. Firms without manufacturing departments (products processed by other firms in India.):										
	9†	1,42,89,400	2,39,06,010	7,40,750	38,30,100	8	43	51	29,17,586	11.5
TOTAL	28	6,90,38,390	13,13,49,310 (61,35,950 being of cosmetics).	59,72,300	4,17,15,850	354	3,126	3,480	1,04,16,016	9.88 (average)

\* 5 not registered under the Industries (D. & R.) Act, 1951.

† All of them not registered under the Industries (D. & R) Act, 1951.

1.4. A majority of these concerns process mainly imported bulk pharmaceuticals into compounded preparations, tablets, ointments, injectibles etc. As a result of these activities, they provide employment for 3,500 to 4,000 Indian citizens, draw upon indigenous resources of packaging material such as glass containers, cardboard cartons etc., and other raw materials to the value of about Rs. 60 lakhs per annum and help to a certain extent to raise the standard generally of pharmaceutical products and packaging material made in the country. Similar processing work is also carried on by a large number of Indian firms. Therefore, their activities do not really come under the category of new lines of production. The type of processing work at present carried out also does not involve, in majority of cases, special types of experience and technical skill, which the indigenous industry cannot undertake. Several protests have been received from the Indian manufacturers against this activity of foreign firms processing bulk pharmaceuticals. In view of the long association of their names and labels with the consuming public in the markets of this country, their products command respect and confidence of a majority of prescribers, dispensers and users of drug preparations, and are preferred very often over drugs processed by Indian firms, and this forms the main cause for these protests. Since a large number of these firms had not seen the need for putting up the processing departments or undertaking processing work as long as their finished products were allowed to be freely imported into this country, and have started processing activities only recently, a section of the Indian industry considers that these activities of foreign firms are a sequel to the changed import policy of the Government, which has been necessitated by the balance of payment considerations of the country. It has been suggested by them that foreign firms should not be allowed to undertake processing of bulk pharmaceuticals, but only allowed to produce bulk pharmaceuticals for processing of which ample capacity with the Indian firms already exists. Once a foreign firm has been allowed to establish itself in this country, no discrimination can be made as regards its activities. The suggestion that the activity of the foreign firms should be restricted merely to the production of bulk pharmaceuticals to meet the requirements of these products of Indian firms, which ... processing work is therefore hardly tenable. The foreign firms want to maintain the markets, which they have developed for their products, and as such supply of drugs in a finished form is the main incentive for all their investments on manufacturing units within this country. While there should be no objection for their maintaining production of finished products to meet these markets, they should not restrict their activity to only this sphere, and make the country entirely dependent on foreign imports of bulk pharmaceuticals. The imports of drugs have been mounting steadily in spite of the fact that a large number of pharmaceutical firms have come into existence in the recent past. We do appreciate, that until such time, as the personnel get trained on processing work, auxiliary industries develop to meet the needs of packing material etc., and distribution machinery gets organised to ensure proper markets for the products, the investors would be hesitant to invest more capital on complicated machinery and equipment for the actual production of the pharmaceutical within the country. But this should not be allowed to go on indefinitely.

...



1.5. They should progressively extend their manufacturing activities to include the production of bulk pharmaceuticals starting from basic chemicals and/or intermediates as near to the basic chemicals as possible. All of them possess the necessary experience and capital resources for undertaking such work, and have excellent research establishments in their own countries to tackle problems that may be met with in developing such production. Certain difficulties like the availability of raw materials, lack of sufficient demand for establishing economic production etc., may be experienced in the beginning. The lack of raw materials should be overcome by allowing freely their imports, until such time as their production actually develops within the country. Once a demand is created for them, it forms the best incentive for their production to be developed. While planning the production of bulk pharmaceuticals, the production capacity should not be confined merely to the requirements of the particular factory but should be large enough to be able to supply as far as possible the requirements in the country.

1.5.1. The size of an economic unit, as envisaged in foreign countries, does not apply *in toto* for conditions existing in India. Lack of sufficient demand at the moment to justify such economic units should not therefore deter firms from putting up units, for their manufacture within the country. Even if the demand for an essential product is slightly lower, to warrant an economic production within the country, its production should be undertaken and the Government should give protection to the industry to withstand foreign competition, until such time as the demand rises to an economical level. The choice for the development of any such product should be left entirely to the manufacturers concerned depending on the facilities they possess for such development, subject to the approval by Government.

1.5.2. No new foreign concerns should be allowed to set up factories unless they undertake to manufacture products which have not been manufactured in adequate quantities by other factories, starting from basic chemicals and/or intermediates as near to the basic chemicals as possible, within a reasonable time. To avoid unhealthy competition at the early stages of development and to ensure the concerns sufficient offtake to justify investments on such manufacture, only a few firms should be allowed to take up the development of the same product.

1.6. Certain class of foreign firms may not be able to change their mode of working into this pattern. For example, some of the foreign firms have got into agreements with Indian concerns for the manufacture of pharmaceuticals in bulk and, in addition, have themselves set up a processing department for converting these pharmaceuticals into a dosage form. Under these conditions, the activities of their manufacturing departments are restricted mainly to processing and all development work on the manufacture of the pharmaceuticals is left to the Indian concerns, with whom they are in collaboration. It may not be possible for such firms to extend their activities to the manufacture of pharmaceuticals from basic chemicals. In all such cases, such development work will have to be undertaken mainly by the Indian concerns. But these Indian concerns under their terms of agreement are not allowed to sell the bulk chemicals, they produce

to other processors, but only to those processing departments of the foreign firms, with whose collaboration they have undertaken its production. Arrangements made by certain manufacturers, whether Indian or foreign, forbidding the selling of bulk chemicals to other processors based on agreements entered into with foreign firms should be discouraged. These Indian concerns will not be able to extend their production beyond the processing capacity of the foreign firms, with whom they have come to an agreement, and therefore in many cases will not be able to attain economic production.

1.6.1. Certain arrangements have been entered into between some manufacturers in India with firms abroad by means of which, the former are not in a position to undertake the manufacture of other useful and latest drugs, based on the original product prepared in collaboration with the latter. Such arrangements are not in public interest and, therefore, should be discouraged. Even the little capacity, that exists for the production of these essential drugs is therefore being crippled by these business interests of the foreign firms, which try to maintain production of only the products, which are covered by their patent rights. They try to maintain markets for these products by intensive propaganda and advertisement, and are not allowing the collaborating Indian firms to make new products and thus deprive the country of the benefits of the advancements in the field of medicine. Therefore, in all such cases the Indian firms should have full freedom to improve on their products and make use of all the development in the field of medicine.

1.6.2. In practice, this might lead to difficulties like the infringement of patent rights etc. The Patent Law of the country should be amended to secure effective utilisation of all developments in the field of science and medicine, wherever necessary in the interests of the country.

1.7. Another class of foreign firms which may not be able to change their pattern of working in conformity to that recommended are those, which have no processing departments of their own, but get such work done in the manufacturing departments of other firms, which mainly undertake such work or have a surplus processing capacity. These firms, in turn, lease out a portion of their premises and hire the requisite number of persons to process these products. Therefore, these firms which get their products processed at others' premises and factories, have no capital investment of their own in respect of machinery or plant used in their manufacture with the exception of certain punches and dyes to engrave the tablets, labels, etc. We do not see much future for this type of activity. We understand that some of these firms are anxious to put up their own processing departments but such permission has not been forthcoming in view of the surplus capacity for processing work that already exists in this country. Firms which have no processing departments of their own but get such work done at others' factories should be given permission to put up their own departments for the purpose, provided that some of the drugs are of an essential nature and they undertake to produce them, starting from basic chemicals and/or intermediates as near to the basic chemicals as possible, within a reasonable time. Meanwhile, the utilisation of the existing processing capacity of firms

which manufacture products for marketing by firms, owning or leasing trade mark, should be allowed to continue as at present. No further addition to it by Indian, foreign or semi-foreign firms should be allowed.

## 2. Foreign Collaboration:

2.1. In addition to the foreign managed firms in India, which have concluded agreements with their principals or other foreign firms for production of some of their products under royalty terms, some of the Indian firms have also undertaken production of pharmaceuticals under agreements with foreign firms.

All these agreements for collaboration can be broadly divided into 4 types:—

- (i) Agreements with foreign concerns and their Indian subsidiaries (India Ltd.) embodying royalty terms;
- (ii) Agreements between foreign concerns and their branches in India embodying royalty terms;
- (iii) Agreements between foreign firms and Indian firms, in which capital is partly foreign and partly Indian, with royalty payments to foreign firms; and
- (iv) Agreements between foreign firms and Indian firms in which capital is entirely Indian with royalty payments to foreign firms.

The following table shows the names of firms with manufacturing activities in India and names of foreign firms with whom they have entered into agreements, and the products that they have undertaken to produce under these agreements:—

**TABLE No. 21—THE NAMES OF MANUFACTURING FIRMS IN INDIA WHICH HAVE ENTERED INTO AGREEMENTS WITH FOREIGN FIRMS AND PRODUCTS, MADE UNDER THESE AGREEMENTS.**

S. No.	Name of the concern registered as manufacturer in India.	Name of foreign firm in agreement with.	Nature of products made under the agreement.
1	2	3	4
1	M/s Geigy Insecticides Ltd., Neville House, Nichol Road, Ballard Estate, Bombay—1.	M/s J. R. Geigy S.A. Basle (Switzerland).	Formulations of insecticides: (wetttable powders, dust sprays and emulsions).
2	M/s May & Baker Ltd., Worli, Bombay.	M/s May & Baker Ltd., Dagenham, England.	Ephedrine, Sulphapyridine and Sulphathiazole. Processing drugs into injectibles, tablets, emulsions etc.
3	M/s Gladstone Lyall & Co. Ltd., 4, Fairlie Place, Calcutta-1.	M/s J.R. Geigy S.A. Basle (Switzerland).	Formulations of insecticides.
4	M/s British Drug Houses (India) Ltd., Imperial Chemical House, Ballard Estate, Bombay.	M/s British Drug House Ltd., London.	Galenicals, Cosmetics. Processing drugs into injectibles, tablets, etc.

1	2	3	4
5	M/s Parke Davis & Co., Ltd., Canada Building, Hornby Road, Bombay.	M/s Parke Davis & Co. Ltd., Detroit.	Intend producing chlo-romycetin, Liver extract, malt products etc. and processing drugs.
6	M/s Group Laboratories (India) Ltd., 191, Pitamber Wadi, Opp. L.J. Road, Mahim, Bombay-16.	M/s Beecham Group Ltd., London.	Cosmetics like toothpaste Brylcream, compounded, preparations like fruit-salts and stomach powder.
7	M/s Nivea Pharmaceuticals, Clive Building, Netaji Subhas Road, Calcutta.	M/s Herts Pharmaceu-ticals Ltd., England.	Processing anti-T.B. drugs like P.A.S.
8	M/s Boots Pure Drug Co. (India) Ltd., Bombay.	M/s Boots Pure Drug Co., Nottingham, England.	Processing drugs into tab-lets, liquids, powders, ointments.
9	M/s. Ciba Pharma Ltd., Es-planade House, Waudby Road, Bombay.	M/s Ciba Ltd., Basle (Switzerland)	Processing drugs into tab-lets, injectibles, oint-ments, powders, liquids. etc.
10	M/s Cilag Hind Ltd., Mehar House, 15, Cowasji Patel St., Bombay-1.	M/s Cilag Ltd., Switzerland.	Processing of drugs like P.A.S. Sulphadimethyl pyrimidine, Sulphaguani-dine and Sulphanilamide.
11	M/s Biochemical & Synthetic Products Ltd., Hyderabad.	M/s Cilag Ltd., (Swit-zerland) through M/s Cilag Hind Ltd., Bombay.	Intend processing sulpha drugs, Anti-T.B drugs (PAS/INH) etc.
12	M/s Manufacturing Analy-tical & Research Chemists (M.A.R.C.) Ltd. Esplanade House, Waudby Road, Fort, Bombay. (Owned by M/s Ciba Pharma Ltd.)	M/s Ciba Ltd., Basle (Switzerland.)	Producing cosmetics and processing drugs & pharmaceuticals.
13	M/s Geoffrey Manners & Co. Ltd., Magnet House, Dougal Road, Ballard Estate, Bom-bay.	1. M/s White Hall Pharm Co., New York. 2. M/s Scrubb & Co. Ltd., London. 3. M/s John Wyeth & Brothers Ltd., London. 4. M/s Chesebrough Manufacturing Co., New York. 5. M/s McKennon Harrison Ltd., Montrical. 6. M/s International Chemical Co., Bombay.	Patent and proprietary medicines and cosmetics.
14	M/s Glaxo Laboratories (India) Ltd., Worli, Bombay.	M/s Glaxo Laboratories Greenford, Midd-lesex, England.	Processing drugs into in-jectibles, tablets, liquids, ointments and filling of anti-biotics.

1	2	3	4
15	M/s Atul Products Ltd., Parnera, Bulsar.	M/s American Cyanamide, Co. U.S.A. (through M/s Lederle Lab. (India) Ltd., Bombay.	Manufacture in bulk sulphadiazine, Folic acid and Aureomycin.
16	M/s Atul Products Ltd., Parnera, Bulsar.	M/s Ciba Ltd., Basle (Switzerland) through M/s Ciba Pharma Ltd., Bombay.	Manufacture in bulk Sulphathiazole.
17	M/s. Lederle Lab. (India) Ltd., Bulsar.	M/s American Cyanamide Co., New York.	Processing drugs like sulphadiazine, aureomycin and folic acid and compounded preparations.
18	M/s. Sarabhai Chemicals, Baroda.	M/s E.R. Squibbs & Sons, New York.	Filling antibiotics, processing drugs into tablets injectibles, etc. and producing Anti-T.B. drugs, calcium preparations, etc.

2.2. These agreements include widely varying terms, and no definite guiding principles appear to have been followed while drawing them up. In many cases, foreign firms are allowed the exploitation of the markets with local co-operation on unessential items such as tooth pastes, face creams, balms, laxatives, cough syrups etc., which certainly do not call for foreign collaboration for their manufacture in India. The payment of royalties vary considerably from 12 per cent. to 15½ per cent. even for more or less similar products. The basis, on which these royalties are to be paid also differ and the period of validity of these agreements vary from 1 to 20 years. In some of the agreements, there are no stipulated payments of royalty or selling rights and no apparent financial benefit to the foreign collaborator. These agreements appear to be unusual needing further scrutiny.

2.3. Even in the case of production of essential drugs and pharmaceuticals, the agreements refer only to "know-how" of their processing i.e., ampouling, granulating, tableting etc., or compounding of imported pharmaceuticals, but not to their manufacture from basic ingredients. These royalty payments amount sometimes to as high as, 12½ per cent. which have been stipulated as royalty for the supply of blueprints and other engineering facilities and advice in the country of the foreign firm for the supply of the "know how". Such huge royalties on finished products imported in bulk and only repacked in this country seem unwarranted.

2.4. Even in the case, where provision for the manufacture of pharmaceuticals starting from basic chemicals have been mentioned, the actual manufacture has stopped at a stage of converting the penultimate product to the final product. The agreements are very vague and there is no definite guarantee that the manufacture will be progressively improved to commence from basic chemicals. There are only general undertakings that they will improve it by one step and that too only at the discretion of the foreign firm.

2.5. In some agreements payment of royalty has been stipulated for the distribution rights in this country of finished products ready-packed for the market. In such cases, the question of a "knowhow" or technical help does not arise; and it only means a payment of royalty by the party, who by all rights, should receive a commission for its services.

2.6. Where drugs are manufactured in bulk under payment of royalty, the agreements stipulate that the manufactured drugs should be only sold to one party or to their nominees at prices stipulated by them. We have already discussed this aspect and consider such terms undesirable as they create monopolies and are not in the best interests of the development of the pharmaceutical industry in this country.

2.7. In some of the agreements, the purchase of raw materials from the foreign principals forms an integral part of the agreement and where such purchase is not made the royalties are doubled. Such clauses limit the freedom of the concerns from purchasing raw materials from the cheapest sources and are against the interests of the industry in the country and should be removed as soon as possible.

2.8. In future, all such agreements should be thoroughly scrutinised by Government and the following guiding principles adopted in permitting collaboration with foreign firms. The existing agreements should also be revised at the earliest opportunity to be in conformity with them:—

- (i) No foreign collaboration should be entertained only in respect of cosmetic items such as tooth paste, eau-de-cologne shaving creams etc.;
- (ii) Generally, foreign collaboration should be allowed only when a firm is agreeable to commence with the manufacture of at least a few basic drugs from primary raw materials;
- (iii) Permission may be granted for compounding of selected drugs on basis of essentiality provided the firm agrees to complete its programme of manufacture of basic drugs within a specified period; and
- (iv) The scheme of licensing should, as far as possible, be so evolved as not to give a monopoly to any one firm, but keep competition alive. In approving schemes for the manufacture of basic drugs, care should, however, be taken to see that the production of the same drug is not taken up by too many firms.

2.9. The order of preference for foreign collaboration should be as follows:—

- (i) Products manufactured wholly in India from basic raw materials of mainly Indian origin;
- (ii) Products for the manufacture of which the basic chemicals and/or intermediates as near to the basic chemicals as possible are imported.

- (iii) Products in which the finished drugs are imported in bulk and processed into pharmaceuticals here and packed; and
- (iv) Finished products imported in bulk and only repacked here for sale.

In future, there should be little scope, if any, for collaboration with any foreign concern, of the type given under (iii) and (iv) above.

2.10. Although, the ideal and ultimate aim should be the manufacturing of all products in India from the basic primary factors, and putting all stages of the manufacturing of the finished pharmaceuticals in India, it should, however, be borne in mind that it is not possible to do away immediately with imports of the finished products especially the synthetic drugs, antibiotics, vitamins and hormones considering that these are essential in the practice of modern medicine. Their imports should be gradually reduced and the existing processing capacity of the country should be utilised fully, by importing them in bulk and processing them out till such time as their production develops in the country.

2.11. *Capital Structure.*—The Committee is of the opinion, that where foreign firms have contributed part of the capital, their general interest in the welfare and development of the Indian concern is certainly greater and their stakes in this country are also to some extent higher. Therefore, “tie-ups” with foreign firms including participation in capital should be preferred to “tie-ups” with no foreign participation in capital. In the pharmaceutical industry, however, foreign capital participation should not generally exceed 49 per cent.

2.11.1. *Firms with 100 per cent. foreign capital*—the so-called “India Ltd.”—and also branches of foreign firms with 100 per cent. foreign capital should not be permitted to be established. Under exceptional circumstances, permission for the establishment of such firms may be granted for the manufacture of basic chemicals and drugs which the Indian managed factories are not able to take up. The desirability of insisting on participation of Indian capital in cases where the manufacturing process is completed might be considered with a provision for repatriation of foreign capital from the sixth to the fifteenth year thereafter. This would ensure that foreign collaboration is kept interested in the success of the undertaking.

2.12. *Royalty.*—In one case reviewed by the Reserve Bank of India, it is recommended as follows:—

“No royalties should be paid on any product unless a list is furnished and the Ministry of Commerce and Industry certify that there is no current production of these items in the country except under a royalty payment.”

The Committee is of opinion that this is a sound general principle which should be adopted.

2.12.1. The manufacturing operations should be divided into:—

*Essential.*—Drugs like hormones, vitamins, antibiotics etc., and also those used in the treatment and prevention of diseases; and

*Not essential.*—Products like pick-me-ups, tonics, patent and proprietary medicines of a general nature, household remedies, tooth pastes, shaving soaps, talcum etc.

Royalty rates should be worked as under:—

Essential	... Not exceeding 5 per cent.
Not essential	.. Not exceeding 2 per cent.

2.12.2. It is felt that payment of rates of royalty for “pure know-how” as agreed by some firms is excessive and this should be reduced to a reasonable figure, when current agreements come up for revision.

2.12.3. Where royalties are to be paid for the manufacture of basic drugs, these should be calculated not on the value of the finished products but on the bulk basic drug.

2.12.4. Payment of royalties for the exploitation of a registered trade mark or proprietary name should be discouraged. Where such royalties are paid, they should not exceed  $3\frac{1}{2}$  per cent. of the value of bulk basic drug. In all cases, the royalties payable should be scaled down on the basis of the turn over as under:—

“Maximum agreed figure on net sales of Rs. 1,00,000 per year diminishing progressively year after year on sales upto Rs. 5,00,000 beyond which 2 per cent. should be fixed.”

2.13. *Period of Agreement*—Generally speaking, agreements should be revised every five years, although in special cases, Government may permit agreement for a longer period initially.

2.14. In future agreements, clauses which (i) prevent the purchase of machinery, raw materials or packing materials from the best available source; and (ii) restrict the sale of a drug manufactured under a royalty to any particular party or their nominee, should not be allowed.

2.14.1. In all agreements, suitable provision should be made for training of Indian personnel. In respect of agreements already in existence, where the recommendations made in this report have not formed the basis of such agreements, Government should take appropriate action to get them modified at the earliest opportunity.

### (iii) LARGE SCALE PRIVATE ENTERPRISE UNDER INDIAN MANAGEMENT

#### 1. General:

1.1. Large Scale Private Enterprise under Indian Management can be classified as under based on the nature of pharmaceuticals they make:

- (a) Manufacturers and/or processors of drugs;
- (b) Manufacturers of disinfectants, insecticides and their formulations; and
- (c) Manufacturers of surgical dressings.



1.2. Some of these firms carry out the manufacture and/or processing of pharmaceuticals as their main activity, while others as adjuncts to the manufacture of heavy chemicals, dyestuffs etc. The activities of certain firms entitle them to be included in more than one of the above categories and a few of them among all the three. The following table shows the details of firms which have been registered under the Industries (Development and Regulation) Act, grouped under the above categories:—



सत्यमेव जयते

**TABLE NO. 22.—THE CAPITAL INVESTED, LABOUR EMPLOYED, VALUE OF RAW MATERIALS CONSUMED, SALE VALUE OF FINISHED PRODUCTS ETC., OF THE INDIAN MANAGED LARGE SCALE PRIVATE ENTERPRISE REGISTERED UNDER THE INDUSTRIES (DEVELOPMENT AND REGULATION) ACT, 1951**

Type of firm	Total No. of firms	Total capital invested (Rs.)	Sale Value of finished products made in 1952 (Rs.)	Value of raw materials consumed in 1952		Labour employed		Expenditure incurred on advertisement in 1952 (Rs.)		% of total sales (average)
				Indigenous (Rs.)	Imported (Rs.)	Technical	Non-technical	Total expenditure	Total expenditure	
1	43	6,90,28,150	10,87,75,073	1,40,44,982	1,89,01,650	816	11,922	12,738	77,75,600	9.35
Manufacture and processing of drugs										
2	4	2,01,28,490	1,93,77,700	18,30,900	25,70,800	217	3,266	3,483	8,000	0.40
Manufacture and processing of drugs in addition to manufacture of heavy chemicals and dyestuffs										
3	2	6,62,600	15,48,300	1,12,300	1,00,500	17	93	110	1,000	10.00
Manufacture of disinfectants and insecticides.										
4	4	27,66,900	41,28,400	13,18,000	7,81,900	26	613	639	1,55,900	2.00
Manufacture of surgical dressings										
TOTAL	53	9,25,86,140	13,38,29,473	1,73,06,182	2,23,54,850	1,076	15,894	16,970	79,40,500	8.90

## (a) MANUFACTURERS AND/OR PROCESSORS OF DRUGS:

### 1. Drugs of Vegetable Origin:

1.1. The manufacture of galenicals is the most common activity of these firms and many of them are able to utilise only 50 per cent. or even less of their installed capacity for this type of work. There is also considerable difficulty in obtaining enough supplies of the right quality of raw materials *viz.*, medicinal herbs. We have dealt later with the steps necessary to overcome this difficulty in the chapter dealing with 'Basic Raw Materials of the Industry'. During the early days of this industry, the production of galenicals formed the main activity of the pharmaceutical manufacturers and this was very much expanded during the last two Wars. But with the advent of chemo-therapeutic products and antibiotics, which have radically changed the mode of treatment of diseases, a large amount of the existing capacity for galenicals has been rendered surplus. Several representations have been made by manufacturers bringing to our notice this wastage of capacity and the continued expansion in this branch of the industry. There is a tendency for all new entrants into the pharmaceutical industry to undertake this type of work. It is not merely confined to smaller firms which have at present no restrictions whatsoever with regard to the type of products they undertake, but also extends to larger units which have to obtain permission under the Industries (Development & Regulation), Act before starting their factories. To withstand competition, the quality of products made is being sacrificed and a race for making cheaper products prevails. We are strongly of the opinion that no new firms should be allowed to start the manufacture of galenicals for which there is already a surplus capacity.

1.1.1. For better utilisation of the existing capacity of the firms and to prevent manufacture of sub-standard drugs, the equipment and staff employed by the firms should be scrutinised. Wherever the required minimum equipment and staff does not exist, the licence under the Drugs Act should be withdrawn.

1.1.2. Extraction of alkaloids barring a few items like quinine, strychnine, caffeine, morphine etc., on the other hand is not being carried out in adequate quantities. With the improvement in the supply position of raw materials which we have referred to already, this branch of the industry is likely to expand. To start with, we recommend that the manufacturing firms should set up properly designed pilot plants and study the economy of their methods of extraction and collect sufficient chemical and chemical engineering data so as to enable them to design and set up plants for their extraction on a commercial scale.

### 2. Drugs of Animal Origin:

2.1. The next common activity is the manufacture of biological products, specially liver extract and vaccines and sera. This is, no doubt, a very welcome development of the industry and should be encouraged to grow on right lines. In the chapter dealing with "Basic Raw Materials of the Industry", the Committee have pointed out the steps necessary for organisation of slaughter houses (i) for making easily available to the industry organs such as glands and

other tissues, which are obtained from slaughter houses; and (ii) for the proper storage and preservation of such organs to avoid deterioration before removal. Many of the factories making glandular products and vaccine and sera are not upto the standard required. The existing equipment for manufacture and testing should be scrutinised and the licence under the Drugs Act withdrawn if proper equipment does not exist or where unhygienic conditions prevail.

### 3. Fine Chemicals and Synthetic Drugs:

3.1. The manufacture of fine chemicals such as ether, chloroform, calcium lactate etc., have been developed to meet a major portion of the country's requirements. Inorganic chemicals such as sodium bicarbonate, magnesium sulphate, ammonium and potassium bromide etc., are also being produced in appreciable quantities by factories, which manufacture heavy chemicals and meet the demand for these products in medicine in addition to their demand in other industries. But the manufacture of synthetic drugs, which forms a very important branch of the industry, exists to a very limited extent. In most cases, it is in the stages of laboratory experimentation, or converting the imported penultimate products into the final product. Even, where commercial production starting from primary raw materials is claimed to have been achieved, the manufacture is being carried out in large size laboratory units, which are a combination of much glassware and rubber with a few key items like reaction vessels in metal. Very often they are not even pilot plants, which will be able to yield basic chemical and chemical engineering data, on which a large scale plant can be successfully designed and built and accurate costing data obtained.

3.2. We recommend that to start with, firms, which want to undertake the manufacture of fine chemicals and synthetic drugs not so far manufactured in India and whose 'know-how' is not easily available, should be required to establish properly designed pilot plants with the help of standard chemical engineering firms and/or national laboratories and collect basic chemical and chemical engineering data, and study the economy of the methods, they wish to adopt, to enable them to put up large scale plants for their commercial production.

3.2.1. A number of firms appear to be trying to develop production of the same or similar items. To prevent such duplication of effort, which may again result in an unplanned expansion of the industry and unhealthy competition, all the firms should be asked to indicate their development programmes for the next 5 years along with the assistance they require from Government for carrying them out. These development programmes should be scrutinised by Government and the firms allowed to take up development of such lines of production for which they are most suited, ensuring simultaneously that all important lines of production are being explored.

3.2.2. Once a development programme of a particular firm has been approved a constant watch on the progress made by it should be kept. The progress being satisfactory, all facilities should be given for its furtherance.

3.2.3. The firms should also be assisted by preventing too many firms from undertaking similar lines of production to ensure a suitable offtake to justify their investments in the new lines of production. This section of the industry needs a properly planned development and the operations of the Industries (Development & Regulation) Act will be able to play an important part in bringing this about.

3.2.4. A large number of firms should not be licensed to carry out almost identical type of work without any regard to the requirements of the country or the already existing capacity as the very object of the Industries (D. & R.) Act will be defeated and the development of the industry retarded.

3.3. Another factor which hinders the development of the synthetic drug industry in the country is the working of the Patent Laws. In almost all cases patents are held by foreign firms and they are either not willing to allow their patents to be worked in India or do so on payment of heavy royalties and by imposing several restrictions in their marketing of these products. The granting of such monopolistic rights for drugs, which are required for saving life, and minimising human suffering is itself a debatable point. In foreign countries patents are considered as very great incentives for research. The pharmaceutical firms spend large sums of money on research with the hope of discovering new drugs, which could be patented by them and thereby make important contributions to the advancement of medicine. But as far as this country is concerned, all these researches are carried out by these firms in foreign countries and only large profits by marketing these products are made in this country. The Government should consider if they can abrogate the International Patent Registrations to enable manufacturers in the country to make essential pharmaceuticals like sulpha drugs, vitamins, hormones etc., without having to pay heavy royalties to foreign firms. A similar step was taken by Japan before the last World War and this helped the drug industry of that country to come up to the level of other advanced countries. Even today, Japan holds an important position in the field of antibiotics and synthetic drugs.

(b) MANUFACTURERS OF DISINFECTANTS AND INSECTICIDES AND THEIR FORMULATIONS:

1.1. The manufacture of disinfectants and insecticides has not received much attention by the pharmaceutical industry. The most common disinfectant made in the country is phenyl from coaltar fractions for sanitation work. The other types of disinfectants are produced, if at all, to a very limited extent. The insecticides made are mostly formulations obtained by mixing various diluents like chalk, calcite, talc etc. to imported insecticidal chemicals such as B.H.C., D.D.T. etc. Only in a few cases are these chemicals being made by the firms. Many of the formulators have no equipment even to verify if the preparations they make are really effective.

1.2. At present, disinfectants and insecticides made in the country have no standards by which their effectiveness could be gauged. It is necessary to lay down standards for disinfectants and insecticides and bring them under the purview of the Drugs Act and thus control their quality.

## (c) MANUFACTURERS OF SURGICAL DRESSINGS:

1.1. The production of surgical dressings was very much expanded during the last War to meet the increased requirements of the Defence Forces. These products were also exported out of the country immediately after the War. But these export markets appear to have been now practically lost and the poor quality of the products that were made and sent out by a large number of manufacturers may be largely responsible for this. Even now as the surgical dressings do not come under the purview of the Drugs Act, no control on their quality is being exercised. A very unhealthy competition exists and the quality is being continuously sacrificed for making cheaper goods. Some of the textile mills and power looms have also undertaken their manufacture and are utilising cotton waste for the purpose. Many of them do not carry out any tests on the quality of the products they sell and some are even unaware of the existence of such tests. To prevent unhealthy competition and deterioration in the quality of the products made it is necessary to enforce strict quality control on the products marketed and withdraw the licence of the firms which do not keep upto the standards laid down. This will help in increasing the production of standard goods, develop in course of time export markets, and lead to the utilisation of the existing surplus capacity for their production in the country.

## (IV) SMALL SCALE PRIVATE ENTERPRISE:

## 1. General:

1.1. There was a great boom for pharmaceutical products during and immediately following the last War, and a number of small establishments for making galenicals and processing drugs into tablets, capsules, ampoules, etc., cropped up in the country. These have been supplemented by more units established by persons who migrated from Pakistan after the partition. The following table shows the number of these units in the different States, the capital invested by them and the sale value and nature of products made:—

TABLE NO. 23.—THE CAPITAL INVESTED, LABOUR EMPLOYED, ANNUAL SALES, ETC. OF SMALL SCALE PHARMACEUTICAL ESTABLISHMENTS (EXCLUDING 18 SMALL SCALE ESTABLISHMENTS UNDER GOVERNMENT MANAGEMENT OR FOREIGN CONTROL)

State	Total number of small scale establishments	Number of small scale establishments from whom replies were received	Total capital invested by firms in Col. 3 Rs.	Value of raw materials consumed by firms in Col. 3.		Sale value of finished products of firms in Col. 3 Rs.	Labour employed by firms in Col. 3.		Total
				Indigenous Rs.	Imported Rs.		Tech.	Non-Tech.	
1	2	3	4	5	6	7	8	9	10
PART 'A' STATES :									
1. Assam . . . . .	11	4	1,17,215	28,890	500	58,000	4	23	27
2. Bihar . . . . .	15	9	2,33,212	46,400	37,030	1,77,899	23	53	76
3. Bombay . . . . .	544	34	89,21,945	12,42,803	19,38,441	88,81,757	89	551	640
4. Madhya Pradesh . . . . .	39	32	3,63,110	1,94,727	91,921	4,91,591	51	114	165
5. Madras (including Andhra) . . . . .	128	33	36,98,704	20,62,936	1,90,212	55,12,542	90	424	514
6. Orissa . . . . .	1	..	NA	NA	NA	NA	NA	NA	NA
7. Punjab . . . . .	37	7	94,100	1,54,100	3,500	46,737	6	..	6
8. Uttar Pradesh . . . . .	142	42	31,95,239	39,49,204	73,620	67,78,267	144	786	930
9. West Bengal . . . . .	536	48	51,85,137	26,12,844	7,25,185	76,95,783	264	1,451	1,715

	1	2	3	4	5	6	7	8	9	10
<b>PART 'B' STATES :</b>										
10. Hyderabad . . . . .		4	4	13,54,000	1,49,333	44,333	8,84,848	12	146	158
11. Madhya Bharat . . . . .		3	3	2,76,083	52,511	12,000	1,28,526	3	19	22
12. Mysore . . . . .		9	2	3,70,000	3,14,690	1,52,110	5,79,860	11	40	51
13. Saurashtra . . . . .		9	7	20,21,342	13,12,268	18,200	23,62,366	86	190	276
14. Travancore-Cochin . . . . .		6	2	4,32,352	1,75,093	35,800	6,14,200	4	34	38
<b>PART 'C' STATES :</b>										
15. Ajmer . . . . .		3	1	2,000	NA	NA	2,400	2	2	4
16. Bhopal . . . . .		3	..	NA	NA	NA	NA	NA	NA	NA
17. Delhi . . . . .		56	32	10,14,110	3,81,987	65,561	10,71,873	45	217	262
18. Kutch . . . . .		2	..	NA	NA	NA	NA	NA	NA	NA
<b>OTHER STATES :</b>										
19. Jammu and Kashmir . . . . .		2	1	12,13,414	2,00,000	1,00,000	4,54,000	23	100	123
<b>TOTAL . . . . .</b>		<b>1,550</b>	<b>261</b>	<b>2,84,91,963</b>	<b>1,28,77,786</b>	<b>34,88,413</b>	<b>3,57,40,649</b>	<b>857</b>	<b>4,150</b>	<b>5,007</b>



1.2. Out of a total number of 1,643 pharmaceutical manufacturers in the country, 1,568 are small scale manufacturers. We have been able to obtain replies to our questionnaire from only 261 out of them. We have been informed by the State Drugs Controllers that these include almost all the important small scale manufacturers in their respective States. The capital invested by these 261 manufacturers works out to Rs. 2,84,91,963, the sale value of products made by them to Rs. 3,57,40,649 and the total labour employed by them to about 5,000. We feel that for the remaining factories which are mostly very small, the capital invested, the sale value of products made and labour employed will not be more than that of these 261 units. A rough estimate concerning these items for all the small scale manufacturers in the country may, therefore, be taken as follows:—

Total No. of small scale manufacturers ..	1,568
Total capital invested by them ...	Rs. 6,00,00,000
Total value of products made by them ...	Rs. 7,00,00,000
Total labour employed by them ...	10,000

1.3. Some of these small scale factories in each of the cities of Bombay, Madras, Calcutta and Delhi were visited by four Sub-Committees formed out of the members of the Committee and by co-opting the local Drugs Controllers as members.

## 2. Location:

2.1. It was found that many of these factories were situated in insanitary places, very often a few rooms in a crowded residential locality or among godowns and other annexes to the main buildings. This was specially so in the city of Calcutta where in addition, the factories were surrounded by stagnant ponds, open drains etc.

## 3. Products Manufactured:

3.1. In the city of Bombay, most of them were engaged in making tablets, in many cases with obsolete machines. Some were producing tinctures, compounded preparations both Ayurvedic and Allopathic, ointments, vitamin preparations etc. A few of them were also making injectibles, and liver extract (both oral and injectible) in addition to the above products. In some cases, the main activity of these firms was only repacking. A few of them, which were making injectibles had ampouling sections, which though small, were properly planned, provided with modern equipment, air-conditioned and kept clean and hygienic. In most of the factories, the existing capacity for processing drugs was not fully utilised and more than half of it was surplus and lying idle.

3.2. In the cities of Calcutta and Delhi, the activities of these manufacturers comprised of making tinctures from botanical drugs, tablets, Ayurvedic and other compounded and proprietary preparations. Many of the proprietary preparations simulated those imported or made by bigger concerns, which had established reputation in the market. Their other products consisted of distilled water ampoules, other chemical solutions for injections, liver extract etc. For tableting, encapsulation etc., they had equipment of the most

antiquated type. The firms which were making injectibles had no equipment for washing ampoules. Mostly these were filled as they were received from the ampoule-makers or at the most after rinsing them with a little water. The rooms, where the ampoules were filled were unkempt and dirty, with cobwebs hanging from the ceiling, and the floor wet with rinsings from the ampoules and other spillings during the filling operations. The rooms were not air-conditioned and were extremely hot with several burners working in full blast. The filling, which was done manually with the help of an inverted flask, a rubber tube and a pinch cork, was carried out by staff mostly dressed in rags and dripping with perspiration.

3.3. The firms in Madras were making similar product such as tinctures from botanical drugs and compounded preparations by mixing different ingredients according to the prescriptions maintained by them.

#### 4. Staff and Testing Facilities:

4.1. In most cases, the manufacture of drugs in these factories was not supervised by technically qualified staff. In order to fulfil the provisions of the Drugs Act, the same qualified man was mentioned as their chemist by a number of firms. As it is well nigh impossible for one man to supervise the manufacturing operations of several factories situated at great distances from each other, most of the manufacturing operations were being carried out without any proper technical supervision. Most of the factories had no testing laboratories to check the quality of the raw materials purchased by them or their finished products sent out into the market. Most of the ingredients used for the manufacture of their products were purchased by them locally from small traders on whose words the strength and potency of their preparations were evaluated. Since there was no check on the quality of the products traded by these small firms, the preparations made out of them by the manufacturers could not be relied upon to be in conformity with the composition specified on the labels.

#### 5. Scope for improvement:

5.1. The manufacturers are working on a very small margin of profit due to the existing cut-throat competition prevailing among them and very few of them have any resources to equip themselves better or buy raw materials of standard quality. Most of their products are made from ingredients that they can buy at the cheapest price in the market. We do not see much scope for these factories, if they continue in the present state. The earlier they get together and work on a co-operative basis as larger and better equipped units by pooling their resources the better will it be for these manufacturers and the public at large. In the continuance of these small scale factories in the present state there is a grave danger to the health of the public. The Government should, therefore, take early steps to cancel licences and close down all pharmaceutical establishments which do not possess the minimum requirements of premises, equipment and staff that the Committee has specified in the succeeding paragraphs. New factories should not be licensed unless they fulfil these requirements.

5.1.1. Considerations like unemployment, labour unrest etc. should not come in the way of compulsorily closing down factories which are definitely below par. Other alternative avenues of employment will have to be sought for solving such problems. However, to prevent hardships that may result from it to small scale manufacturers, they should be induced to get together and by pooling their resources, put up properly equipped co-operative units. If the small firms coalesce into bigger and better equipped units they will be able to employ most of the labour and absorb even more as they expand their activities.

5.1.2. In the alternative, each small scale manufacturer should try to specialise in a particular type of product, after properly equipping himself for its manufacture instead of all of them trying to make a number of products without proper equipment, supervision and control as at present.

## 6. Minimum Requirements:

6.1. To assist the authorities to scrutinise the facilities available with the existing factories licensed to manufacture drugs, and also new factories that may come up for licence, we give below broad outlines of minimum requirements of premises, equipment, qualified staff and testing facilities. These requirements are the basic minimum and the factories, which do not possess them should not be allowed to continue to manufacture, if they are already doing so, or allowed to start manufacture, if they are new factories.

### (i) REQUIREMENTS OF FACTORY PREMISES:

(A) *Location and surroundings*.—The factory should not be situated adjacent to an open sewage drain, public lavatory or any factory which produces a disagreeable odour or large quantities of soot or smoke. The factory should, as far as possible, be located in a sanitary place remote from filthy surroundings.

(B) *Buildings*.—The buildings used for the factory shall be constructed so as to permit of hygienic production. They shall conform to the conditions laid down in the Factories Act 1948, as amended and modified from time to time. The part of the building used for manufacture shall not be used as a sleeping place and no sleeping place adjoining to it shall communicate therewith except through the open air or through an intervening open space.

(C) *Water Supply*.—The water used in manufacture shall be pure and drinkable quality, free from pathogenic micro-organisms.

(D) *Disposal of Waste*.—Waste water and other residues from the laboratory which might be prejudicial to the workers or to public health shall be disposed of in such a way that they are rendered harmless.

(E) *Health, Clothing and Sanitary requirements of the Staff*.—All workers should be free from contagious or obnoxious disease. Their clothing shall consist of a white or coloured uniform suitable to the climate, and shall be clean. Adequate facilities for personal cleanliness, e.g., facilities with clean towels and soap and handscrubbing brushes shall be provided for each sex.

(F) *Medical Services*.—Arrangements shall be made by the manufacturer to provide adequate facilities for first aid and medical inspection of workers and for sanitary inspection of the factory premises. Preventive inoculation and vaccination against the enteric groups of diseases, small-pox and tuberculosis should be carried out wherever possible. The manufacturer shall take all necessary precautions for protecting the life and health of the workers including measures to avoid industrial accidents or diseases.

(ii) MINIMUM REQUIREMENTS OF PLANT AND EQUIPMENT

(A) *Equipment for the manufacture of Ointments, Emulsions, Lotions and Suspensions*:—

1. Mixing tanks.
2. Jacketed kettle, steam gas or electrically heated.
3. A suitable power driven mixer.
4. Storage tanks or pots.
5. A colloid mill or a triple roller mill/or an ointment mill.
6. Liquid filling equipment.
7. Jar or tube filling equipment.

A minimum area of 300 sq. ft. is considered necessary to allow for the basic installations.

(B) *Equipment for the manufacture of Syrups, Elixirs and Solutions*:—

1. Mixing and storage tanks.
2. Portable mixer.
3. Filter press or metafilter or 'Sparklet' filter or other suitable filtering equipment.
4. Vacuum or gravity filter.
5. Deioniser or Water still.
6. Bottle cleaning and drying equipment.

A minimum area of 300 sq. ft. is considered necessary to allow for the basic installations.

(C) *Equipment for the manufacture of Pills and compressed Tablets including hypodermic Tablets*.—For efficient operation, the tablet production department should be divided into three distinct and separate sections:—

- (a) Granulating Section
- (b) Tableting Section.
- (c) Coating Section.

The following minimum equipment is considered necessary in each of the three sections:—

(a) *Granulating Section*:

- (1) Disintegrator.
- (2) Powder Mixer.

- (3) Mass Mixer.
- (4) Granulator.
- (5) Ovens, thermostatically controlled.

(b) *Tableting Section:*

- (1) Tablet machine, single punch or rotary.
- (2) Pill machine.
- (3) Punch and die storage cabinet.
- (4) Tablet counter.

It is desirable that each tablet machine is connected to an exhaust system or isolated into cubicles to prevent general dustiness and contamination.

(c) *Coating Section:*

- (1) Jacketed kettle, steam, gas or electrically heated, for preparing coating solution.
- (2) Coating pan.
- (3) Polishing pan.
- (4) Heater and exhaust system.

Coating Section should be made dust free and suitable exhaust provided to remove excess powder and the fumes resulting from solvent evaporation. A minimum area of 300 sq. ft for each of the above three Sections is considered necessary for basic installation.

For the manufacture of Hypodermic Tablets, a separate room should be provided with glazed walls; and the granulation, tableting and even packing should be done in this room and should not be mixed with the general tableting section.

(D) *Equipment for the manufacture of Parenteral preparations.*—The whole process of the manufacture of parenteral preparations may be divided into the following separate operations:—

- (a) *Preparation of the containers:* This includes, cutting, washing and drying or sterilisation of ampoules or vials, prior to filling.
- (b) *Preparation of solutions:* This includes preparation and filtration of solutions.
- (c) *Filling and sealing:* This includes filling and sealing of ampoules or filling and capping of vials.
- (d) Sterilisation.
- (e) Testing.

The following basic hygienic requirements of this Section should be attained:—

- (1) Strict sanitation throughout the entire plant in order to prevent contamination and to block out pyrogen.
- (2) The preparation room where the solutions are prepared should be tiled and kept immaculate. This room and the room where the solutions are filtered should be air-conditioned.

- (3) The filling and sealing rooms should like-wise be air-conditioned under positive pressure with air locks provided to prevent the entry of air from the outside. The walls and floors should be tiled so that they may be sprayed down with anti-septic solution for cleaning. The benches shall have stainless-steel tops.
- (4) In the room provided for aseptic filling and sealing a sufficient number of sterilising lamps should be mounted over the benches and in the air lock leading to the room to prevent contamination.
- (5) A separate room should be provided for sterilisation, testing (for leaks and floating particles) and drying.
- (6) A cool dry area should be set aside for the storage of the finished product.

The following minimum equipment is considered necessary:—  
*Manufacturing Area:*

1. Storage equipment for ampoules and vials.
2. Ampoule washing and drying equipment.
3. Dustproof storage cabinets.
4. Water still.
5. Mixing and preparation tanks or other glass containers.
6. Filtering equipment such as filter press or sintered glass funnel.
7. Autoclave.

*Filling and Sealing Room:*

8. Benches for filling and sealing.
9. Filling and sealing unit.

*Aseptic Filling and Sealing Room:*

10. Bacteria-proof filters such as Seitz filter, filter candles or sintered glass filters.
11. Filling and sealing unit.

*General Room:*

12. Inspection table.
13. Leak testing equipment.
14. Storage equipment including refrigerated storage, if necessary.

A minimum area of 600 sq. ft., partitioned into suitable size cubicles, is considered necessary to allow for the basic installation.

#### ~ (iii) STAFF

Each of the abovementioned four Sections shall be under the supervision and control of at least one competent Pharmaceutical Chemist holding the following qualifications:—

1. A graduate in Pharmacy or Pharmaceutical Chemist of a University recognised by the Central Government for the purposes of the Drugs Rules;

Or

2. A graduate in Science who for the purposes of his degree, has studied Chemistry as a principal subject and has had at least two years' practical experience in the manufacture of drugs.

The exact number of Pharmaceutical Chemists required for each Section may be determined at the discretion of the Licensing Authority depending on actual production capacity.

#### (iv) TESTING FACILITIES

It would not be possible to lay down general minimum requirements, as the needs of each manufacturer would be different. Under the Drugs Rules, the following requirements have been laid down in respect of testing facilities for raw materials and finished pharmaceutical products:—

“The licensee shall either (i) provide and maintain an adequate staff and adequate premises and plant for carrying out such tests of the strength, quality and purity of the substance as may be required to be carried out by him under the provisions of Part X of these Rules, including proper housing for animals used for the purpose of such tests, or (ii) make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by that institution.”

The above requirements should be rigidly enforced. In the interest of proper quality control the Testing or Control Laboratory in each factory should be separate from the manufacturing section and independent of it. The head of the Control Laboratory should be responsible to the management direct and should not be under the executive control of the Production Manager or the Chief Chemist.

6.2. If a manufacturer intends only to put up a single section the minimum requirements of that section alone should apply. To avoid hardship to small manufacturers in deserving cases, a time limit not exceeding one year may be given to them for improving their existing facilities. Those firms which fail to comply with the minimum standards laid down within the stipulated period should be given the option of continuing their manufacture under a loan licence in the premises of a factory which have the requisite facilities. This will also help the maximum utilisation of the existing plant capacity and reduce hardships to small manufacturers to a minimum at the same time. No latitude should be allowed while licensing firms for the manufacture of medicines for internal use specially those meant for parenteral use.

6.2.1. A group of firms may be encouraged to join together and put up well-equipped testing laboratories for keeping a control on their raw materials and finished products.

6.3. We reiterate that the best way that the small scale manufacturers should adopt is by getting together and pooling their resources to put up well-equipped co-operative units for carrying out manufacture of the various products under proper supervision and hygienic conditions. Failing this, they should distribute among themselves their existing activities and specialise in a particular type after providing themselves with the required facilities. The strict enforcement of the minimum requirements that we have suggested will help them in taking these steps.



सत्यमेव जयते



## CHAPTER III

### BASIC RAW MATERIALS AND PACKING MATERIALS OF THE INDUSTRY

#### (a) BASIC RAW MATERIALS OF THE INDUSTRY

##### 1. General:

1.1. The basic raw materials required by the pharmaceutical industry cover a wide field. They consist of substances of vegetable origin like medicinal plants and plant products; of animal origin such as glands, tissues, etc.; organic solvents, such as alcohol, acetone, carbon disulphide, carbon tetrachloride, chloroform etc.; inorganic acids and bases; coal tar products such as benzene, toluene etc.; and other organic and inorganic chemicals.

1.2. We have dealt in the following paragraphs with some of the important basic raw materials in the supply of which the industry is experiencing difficulties. These have resulted mainly by the absence of their sources in the country. But even in cases, where their sources exist, difficulties in their supply seem to have appeared as their methods of collection and marketing have not been organised on proper lines or as a result of too rigid a control exercised on their use by the Government in the interest of revenue and other factors.

##### 2. Medicinal Plants:

2.1. India abounds in medicinal plants and more than 75 per cent. of the drugs of vegetable origin mentioned in the British Pharmacopoeia are available in the country. The distribution of the more important of these plants is given in Appendix No. 6.

2.2. Most of them are collected from forests, where they grow wild and supplied to drug manufacturers in the country or exported. Very little attempt has been made to cultivate them in an organised way. The trade in these crude drugs is in the hands of unqualified people, who are not always able to distinguish the correct variety and hence mix up a number of them during their collection. They also do not take proper care during storage with the result that very often the active principles are lost, before they reach the pharmaceutical manufacturer. The present uncontrolled and unrestricted way of collecting these herbs has led to a considerable depletion in these plants in the forests, as also a fall in their active principles. The traders also stoop to such unfair tactics as adulterating them with useless herbs to compete in the market. These deplorable conditions in the supply of the crude drugs exist all over the country and almost all the manufacturers have complained about it and asked for steps to be taken to improve the position.

2.3. To ameliorate these conditions we feel that the Government should take immediate steps to organise their cultivation in a scientific manner and sponsor agencies for their proper collection, storage and

marketing. We are glad to note that some of the States *viz.*, Jammu and Kashmir, Madras, Assam and Bengal have set up experimental farms and have also undertaken researches in their cultivation.

2.4. In Kashmir a 250 acre farm has been established in Yarikhah, where cultivation of *Atropa Belladonna*, *Atropa accuminata*, *Hyoscyamus niger*, *Digitalis purpurea*, *Digitalis Lanata* and *Pyrethrum* is being carried out on a moderately large scale to supply the laboratory at Jammu, which is extracting the active principles of these plants on an industrial scale. In addition, experimental cultivation of a number of exotics such as mint, lavender, *chinopodium ambrides*, *artemisia maritima*, *hyoscyamus miticus*, *ergot* etc. are being tried in the farm. The seeds of these are being procured through the United Nations Educational Scientific and Cultural Organisation (UNESCO) and different Scientific Organisations all over the world. The State Government have also schemes to establish additional farms at other suitable places in Kashmir and in the hilly areas in Jammu in collaboration with the Forest Department.

2.5. In Madras, the Research sections of the Cinchona Department of the State Government have taken up experimental cultivation of medicinal and essential oil plants in the Cinchona Plantations at Anamalai and Naduvattam. The Cinchona Department are anxious to undertake cultivation of these plants on a large scale, as they have enough land for the purpose in the Cinchona Plantations, which is unfit for Cinchona but suitable for such drug farms. They have also surplus capacity in the existing quinine factories for extracting the essential principles of the medicinal plants when grown on a commercial scale. The Committee recommend that the Madras Government should assist the Cinchona Department to establish such farms in these plantations on a large scale as they have enough land in the plantations not suitable for cinchona but fit for cultivation of medicinal plants. Adequate grants should be made available both by the Central and State Governments for carrying out experimental work on the cultivation of medicinal plants.

2.5.1. Extraction of the active principles from the plants grown in these farms should be undertaken in the existing quinine factories. This will add to the economic resources of the State and help to meet the needs of the Pharmaceutical Industry.

2.6. In Assam, a scheme for starting a farm of 140 acres for cultivating *Ipecac*, *Rauwolfia*, *Belladonna*, *Hyoscyamus*, *Digitalis* and other medicinal and economic plants, which have given encouraging results in their experimental plantations has been taken up. The Indian Council of Agricultural Research have also sanctioned a scheme for experimenting on the cultivation of some of the above medicinal plants in collaboration with their main scheme of cultivation. At present all such work seems to be carried out mainly by the Forest Department of the State, which appears to be greatly handicapped for want of suitable technical staff for their proper execution and supervision. The Assam Government should preferably set up a separate department manned with technically qualified and experienced staff to supervise and expand the cultivation of medicinal plants. The State possesses varying soil and climatic conditions from

the hills to the plains and can grow most of the medicinal plants that are, at present, needed by the pharmaceutical industry in the country. With a properly planned effort there is no reason why the State should not produce and supply the major requirements of the pharmaceutical industry in the country.

2.6.1. Additional expenditure that may be involved should not deter them from doing so, as the results that will accrue will add to the economic resources of the State and provide a revenue which will far exceed the expenditure that will have to be incurred at the early stages. As this work is of national importance the Central Government should actively assist the State Government by providing technical supervision and adequate grants for carrying out this work.

2.7. In Bengal, an experimental farm for medicinal plants like *Rauwolfia*, *Ipecacuanha* etc. has been established at Rongo in the Cinchona Plantations near Darjeeling. The steps taken by the Bengal Government for their cultivation are highly commendable. Cultivation on a semi-commercial scale of *Ipecacuanha* has been undertaken and very encouraging results have been achieved so far. We strongly recommend that the farms specially for the cultivation of *Ipecacuanha* should be expanded and the extraction of emetine from *Ipecacuanha* should be taken up at the Government Quinine Factory at Mungpoo. This will help the country to become independent of the imports of *Ipecacuanha* and emetine.

2.8. The various efforts that are at present being made by the State Governments independently and under the auspices of the Central Organisations like the Indian Council of Agricultural Research, the Council of Scientific and Industrial Research etc., we feel, would be able to yield better results if they are co-ordinated properly. An agency for the co-ordination of the various efforts made by the State Governments independently or under the auspices of Central Organisations for the cultivation of medicinal plants should be set up by the Central Government. This agency which should be fully representative of the concerned Departments of the States and the Central Government, should review the work done periodically and suggest future course of action. This will enable the States to share their mutual experiences and profit by it in their endeavour to cultivate medicinal plants.

2.9. In addition to the drug farms, the Jammu and Kashmir State has established centres for the collection of medicinal plants, which grow wild, or are being cultivated by the farmers, and for their marketing on a co-operative basis. With the help of these centres, the right variety of medicinal plants are being collected, stored under proper conditions to prevent their deterioration and are being made available to pharmaceutical manufacturers. It is necessary to start such organisations in other parts of the country as well. There is a tremendous scope for the cultivation and marketing of medicinal plants in various States, particularly in the Kangra Valley of the Punjab, which is very suitable for growing a large number of pharmacopoeial drugs and their substitutes. It is understood that the

Punjab Government are anxious to develop their activities in this field and to take up systematic work for the production and development of the drug resources of the State by establishing experimental farms, suitable testing laboratories and by undertaking research work. The important medicinal plants such as *Atropa belladonna*, *Digitalis*, *Hyoscyamus*, *Artemisia*, etc. could be grown in Kangra District, which when fully developed, could go a long way in meeting the demands of the country. For all this work, adequate funds would be needed, which it may not be possible for the States to provide in full. Under the circumstances it is recommended that the Central Government should give all possible assistance to States such as Punjab, West Bengal, Madras, Assam, etc., which are undertaking the important task of cultivating medicinal plants in their respective areas.

2.9.1. Trade in crude drugs is mainly in the hands of "Pansaris" and "Attaars" who are responsible for creating the various difficulties in their supply which have already been enumerated. We have suggested in the chapter dealing with Administration of Drugs Act that these traders should be licensed and their number limited to those who are in a position to guarantee the quality of the crude drugs that they supply. Every batch of crude drugs supplied by them should carry a report of analysis by a recognised Analyst. At the same time, the pharmaceutical manufacturers should be compelled to buy their requirements only from such licensed dealers. This, if implemented, will help to a great extent in stopping the malpractices that are at present rampant in this trade.

### 3. Ethyl Alcohol:

3.1. Ethyl Alcohol is largely used in the pharmaceutical industry in making spirituous preparations, where it serves as a solvent, or as a preservative or both, and as a starting material in the manufacture of other solvents, anaesthetics, and fine chemicals, such as ether, chloroform, acetone, chloralhydrate, acetic acid etc. The following table shows the total production of alcohol in the different States of the country and the approximate quantity used in the industry, major portion of which is in the manufacture of pharmaceuticals:—

TABLE NO. 24—THE STATEWISE PRODUCTION AND INDUSTRIAL  
CONSUMPTION OF ALCOHOL IN 1951

State	Production of all grades (Proof galls.)		Production of rectified spirit (Bulk galls.)		Consumption of alcohol by all Industries including the pharmaceutical Industry (Bulk galls.)	
1	2	3	4	5	6	7
<b>PART 'A' STATES</b>						
Assam	.	.	.	.	260	5,30,760
Bihar	.	.	.	.	21,100	1,21,500
Bombay	.	.	.	.	13,300	83,000
Madhya Pradesh	.	.	.	.	1,30,000	2,94,100
Madras	.	.	.	.	1,30,000	2,94,100
Orissa	.	.	.	.	1,30,000	2,94,100
Punjab	.	.	.	.	1,30,000	2,94,100
Uttar Pradesh	.	.	.	.	1,30,000	2,94,100
West Bengal	.	.	.	.	1,30,000	2,94,100
<b>PART 'B' STATES</b>						
Hyderabad	.	.	.	.	1,30,000	2,94,100
Madhya Bharat	.	.	.	.	1,30,000	2,94,100
Mysore	.	.	.	.	1,30,000	2,94,100
Pepsu	.	.	.	.	1,30,000	2,94,100

I	2	3	4
Rajasthan . . . . .	(4,72,412)*	(20,111)*	(600)*
Saurashtra . . . . .	..	..	39,000]
Travancore-Cochin . . . . .	12,48,685	47,421	40,100
<b>PART 'C' STATES :</b>			
Ajmer . . . . .	139,387	418	740
Bhopal . . . . .	66,467	..	200
Coorg . . . . .	..	..	..
Delhi . . . . .	..	..	..
Himachal Pradesh . . . . .	1,919	..	..
Manipur . . . . .	..	..	..
Tripura . . . . .	15,593	..	..
Vindhya Pradesh . . . . .	82,875	418	..
<b>GRAND TOTAL</b>	<b>2,56,20,297</b>	<b>44,40,727</b>	<b>340</b>
			<b>8,25,400</b>

\*denotes 1952 production.

3.2. The production of alcohol is adequate to meet the requirements of the industry, but the existing diverse excise rules and regulations in the different States, and varying rates of duty and other charges levied on this commodity have created many difficulties like inter-State barriers in the movement of alcohol and preparations thereof which have adversely affected the industry. With the introduction of prohibition in some of the States, these restrictions have become all the more rigorous and these have seriously interfered with the manufacture of pharmaceuticals where the use of alcohol is involved.

3.3. In 1937, to facilitate movement of medicinal and other preparations containing alcohol from one State to another, a reciprocal arrangement had been agreed upon between the States and the need for obtaining an import permit was done away with. An export pass only had to be obtained by which export from bonded warehouses was made possible. The excise authorities at the place of export, received duty at the rate prevalent in the place of destination and provided copies of the pass for the use of the consignee and the Excise Authorities of the importing State. With the introduction of prohibition, these have been practically abrogated by certain States. The system of import permits has been reintroduced and further restrictions have also been imposed. An importer has now first to apply to the local Excise Authorities for an import permit indicating the alcoholic strength of the preparation and the correct amount of duty for the consignment. After the import permit has been procured, he has to place an order, accompanied by this permit, on the manufacturer who is located in another State. The manufacturer, in turn, has to obtain an export permit similar to the import permit. The duty on the articles ordered for has to be prepaid by an importer, or the exporter has to execute a surety bond for the payment of full duty leviable thereon in favour of the Chief Excise Authority of the exporting State and the importer has also to execute a similar bond for payment of duty on importation in favour of the importing State. The whole procedure is very cumbersome and annoying causing needless trouble to the manufacturers. Preparations containing alcohol imported into the country and for which customs duties have been paid at the port of entry have no restrictions in their movement to any part of the country. This places similar products made in the country at a disadvantage as compared to the imported article. The difficulties arising out of such restrictions, and the lack of uniformity in the policy and rate of levy of excise duty between the States have been examined in detail by the Expert Committee on Excise, who have made certain recommendations for overcoming them in their Report. A summary of their recommendations is given in Appendix No. 7.

3.4. We understand that the transfer of List "relating to the duty on medicinal and toilet preparations containing alcohol" from the States to the Centre is under consideration. In the event of such a transfer and the implementation of the recommendations of this Expert Committee, the difficulties experienced by the Pharmaceutical industry at present would be overcome to a great extent. There has been considerable delay on the part of the Government in giving

effect to the recommendations of this Committee. These recommendations should be implemented immediately to give relief to pharmaceutical manufacturers.

3.5. But even after this, we feel that some of the restrictions imposed by the States where prohibition exists, are likely to interfere in the progress of this industry. For example, in the State of Bombay, in the interests of prohibition, production of rectified spirit has been made a State monopoly and its import from other parts of the country has been prohibited. The pharmaceutical firms in the State which have their own distilleries are not allowed to make rectified spirit for sale to the other pharmaceutical manufacturers but have to restrict it to meet only their own requirements. Distribution of molasses is controlled and its supply is being curtailed to these distilleries although available in plenty, and they are being forced to use sometimes a less suitable raw material like the Mhowa flowers. For the alcohol produced and used in these factories a heavy vend fee is charged. These factors increase the cost of production of alcohol, and place the manufacturers at a disadvantage in the production of pharmaceuticals derived from alcohol, when compared with other firms in the rest of the country. The position of pharmaceutical manufacturers who have no distilleries of their own is much worse as they are being compelled to buy rectified spirit from the Government distilleries at an exorbitantly high rate fixed by the Government of Bombay in addition to paying heavy freight for transportation to their factory premises. The cost per gallon of rectified spirit in the State of Bombay is reported to be more than double the price at which it is available in other States. It is, therefore, impossible for these pharmaceutical factories to undertake the production of solvents and fine chemicals derived from alcohol, although they have other facilities for undertaking such work.

3.6. We also noticed during our visits to the factories in the Bombay State several paradoxes as a result of the policy of the Bombay State Government which illustrate the difficulties of the industry mentioned above. In Baroda, Messrs. Alembic Chemical Works, have a large distillery and are in a position to supply alcohol to all the pharmaceutical works in this city, which are more or less located close to their factory. Because of the monopoly for the manufacture of rectified spirit exercised by the State Government, they are compelled to restrict their production of this commodity to meet only their own requirements, while the neighbouring factories have had to obtain their supplies of rectified spirit from the Government distillery at Nasik at an exorbitantly high price fixed by the Government in addition to paying railway freight. This has not only made the production of alcohol in the distillery of Messrs. Alembics uneconomical, but has increased the price of the raw material required by the neighbouring factories several-fold adding to the problems of transport to the already overburdened railways of the country. Another curious fact that has been brought to the notice of the Committee is that Messrs. Alembics are not allowed to use the alcohol produced by them, in their testing and research laboratories but are compelled to obtain these requirements from the Government distillery at Nasik paying a high price. Similar restrictions also imposed by certain other State Governments in the interests of prohibition on



the supply of alcohol to the industry such as (i) making rectified spirit a monopoly of the Government and insisting that all manufacturers should buy their requirements from Government distilleries only, at high prices, (ii) restricting production of alcohol of pharmaceutical firms which have their own distilleries, to their actual requirements, (iii) controlling the supply of molasses to such distilleries, and (iv) charging heavy vend fee on the alcohol of their own manufacture used in their factory, hamper the development of the industry and should be removed.

3.6.1. Unless the industry is allowed the freedom to purchase all its raw materials from the cheapest source available, it will find it difficult to take up new lines of production and progress on right lines. The State Governments should, therefore, adopt methods which will not cripple the industry and devise other means for the furtherance of prohibition.

3.7. With the introduction of prohibition, the misuse of certain medicinal preparations containing alcohol as 'liquors' has resulted. It is for this reason that the States, where prohibition exists are reluctant to relax the check, they are maintaining in the movement of all medicinal preparations containing alcohol into, and out of, the States, as they fear they will not be then in a position to regulate the sale, possession and illicit consumption of the preparations liable to misuse. We find that many tinctures which are being produced for sale for such illicit purposes are those, for which no standards exist and are not found in the British and other Pharmacopoeias which are in use at present in this country. This malpractice can be minimised considerably by prohibiting the production of such tinctures which are not found in the latest editions of the pharmacopoeias in use. The production of the tinctures, which are in the older editions of the Pharmacopoeias and for which genuine demand for medicinal use exists, could be limited to a scale based on the production and consumption of such tinctures before the introduction of prohibition. On the tinctures which appear in the latest edition of the Pharmacopoeias and are liable to misuse, the duty should be raised to the same level as on pure ethyl alcohol. These tinctures are not many and comprise of the following:—

Tinctura Aurantii.

Tinctura Cinnamon.

Tinctura Cinnamon Co.

Tinctura Card. Co.

Tinctura Limonis.

Spiritus Chloroform.

Spiritus aetheris nitro.

Aqua cinnamon.

Aqua Chloroform Conc.

Aqua Rosae Conc.

Aqua menthipip Conc.

A rise in their cost will not cause any hardships to the public and medical practitioners as the quantities actually used in the prescriptions are so small that there will be no significant rise in the cost of medicines, and at the same time, they will be more easily available, their use as 'liquor' having been curtailed. Steps to prevent the misuse of tinctures, especially in the States where prohibition exists, are summarised as follows:—

- (i) The production of tinctures for which no standards exist and which are not found in the British and other Pharmacopoeias, should be prohibited;
- (ii) The production of tinctures which are in the older editions of pharmacopoeia and for which genuine demand exists, should be allowed to be produced on the basis of production and consumption before the introduction of prohibition; and
- (iii) On those of the tinctures which appear in the latest edition of the pharmacopoeia and are liable to misuse, the duty should be raised to the same level as on pure ethyl alcohol.

3.8. In Bengal, the pharmaceutical manufacturers represented to us that enough alcohol was not available in the State to meet the requirements of the pharmaceutical industry as the State Government had imposed restrictions on its import. Even the existing distilleries in Bengal were not in a position to work to their full capacity as the Bihar Government were not permitting molasses to move out of their State. Supplies of molasses, which were formerly available from Java have also stopped. As a result of the restrictions imposed by the Bihar Government on the export of molasses, the distilleries in Bengal are starved of their requirements of this raw material and several have been forced to close down. The Bengal Government, in turn, are imposing restrictions on the import of alcohol from Bihar. These measures have resulted in the scarcity of supply of alcohol to the existing pharmaceutical factories in Bengal. A better co-ordination between the two States should be brought about and full requirements of alcohol made available to the industry.

#### 4. Methyl Alcohol:

4.1. Methyl Alcohol forms an important raw material of the pharmaceutical industry and is required both as a solvent as well as a starting raw material in the manufacture of synthetic drugs. It is also essential in the preparation of Laboratory reagents. Methyl alcohol or methanol, as it is commonly known, is mainly imported into the country. For some reason or other the Central Board of Revenue of the Government of India have considered this alcohol to be potable and a very high rate of duty at par with other spirits like whisky, brandy, gin etc. is being levied. The Board of Revenue are insisting that methyl alcohol, if it is to be exempted from the heavy duty, has to be used under bond or after mixing a denaturant with it. The manufacture of a product under bond imposes innumerable restrictions in the working of the plant and also increases expenditure on account of the establishment charges on the excise staff and has

never appealed to the manufacturers considering the small quantities required by them to start with. Using a denaturant is also not sensible as it is itself used as a denaturant for ethyl alcohol. Moreover, methyl alcohol has to be in a very pure form both for its use as a solvent and for the synthesis of drugs. Mixing other ingredients as denaturants with it even when these are carefully selected to suit each case, the final product would have to be subjected to further purification. This policy adopted by the Central Board of Revenue has come in the way of firms starting the manufacture of products where methyl alcohol forms the raw material and has thus seriously arrested the progress of the synthetic drug industry in the country. It is surprising that methyl alcohol has been considered to be potable and subjected to these restrictions when it is well known to be poisonous and toxic even in its purest form.

4.2. The only justification for this procedure put forward by the Central Board of Revenue is that Her Majesty's Customs and Excise, London have classified Methyl Alcohol of the grade 'purified to be potable' under spirits and subjected it to the same restrictions and duty. Enquiries from the Customs Authorities in U.K. have revealed that this classification has been maintained by them only as a convenient way of controlling revenue and in effect ensuring that it is used for its proper purpose as will be seen from the following extracts from a letter received from the High Commissioner for India in U.K.:—

"Both crude and potable methyl alcohol may be used as denaturants in the making of methylated spirits. Potable methyl alcohol may also be prescribed as a denaturant for ethyl alcohol where duty-free use of the latter has been authorised."

"Methyl alcohol, whether crude or potable, is an industrial spirit and has no legitimate use as a beverage, being of a toxic nature. The classification of the potable alcohol as a spirit subject to spirits duty is maintained as a convenient way of maintaining revenue control and, in effect, ensuring that it is used for its proper purpose."

4.3. The prevailing conditions in India being quite different from those in the U.K., copying of the procedure adopted by Her Majesty's Customs in the U.K. in the classification of this product in the Customs manual, has had exactly the reverse effect and prevented its legitimate use, that is, its use in the industry of the country. We strongly recommend that the Government should immediately revise the classification of methyl alcohol in the Customs manual and make it freely available to all the industries in the country where they are required. The existing requirements of the product by the industry are small and should be allowed to come in without any restriction.

## 5. Coaltar Products:

5.1. Coaltar products constitute the most important of the raw materials of the synthetic drug industry. Their production in the country has not been properly developed and several factors have contributed to the slow progress of this section of the chemical industry.

5.2. Coaltar, the starting material for the coaltar products, is not available in adequate quantities. Whatever is available, is also not of a suitable quality. The composition of the coaltar which is a byproduct of the coking industry depends mainly on the nature of coal carbonised, type and design of coke ovens or coking retort, and temperature and rate of coking. The average Indian coal is of a poor grade with a high ash content and the yield of tar and its quality are low, particularly when compared to the tar recovered from coal in other industrially advanced countries like the U.K. and the U.S.A. 90 per cent. of the coaltar recovered in India is from coke ovens designed and operated to produce metallurgical coke required by the Iron and Steel Industry. The production of metallurgical coke necessitates coking at high temperatures and in the coaltar obtained as a byproduct, the primary paraffinic hydrocarbons present, during the high temperature reached get polymerised to naphthalene hydrocarbons depleting them of the more important coaltar products required by the pharmaceutical industry. All the coke ovens do not have the necessary units for the recovery of benzol, and few of them have rectification units for the production of benzene, toluene and solvent naphtha from the benzol recovered. Some of the steel companies burn the coaltar obtained in their open hearth furnaces, which practice came into vogue increasingly during the war years, when fuel oil was scarce but is being continued even now, because of the prevailing high prices of fuel oil. The steel companies have no incentive to replace it with fuel oil, also because, the coaltar which forms a waste product for them, does not fetch remunerative prices in the market and in some ways is preferable to fuel oil for the production of steel. Coaltar obtained from coking retorts worked for the production of coal gas, is small and in this case as the temperatures reached are also high, the tar obtained is in no way more suitable. The distillers of coaltar are not working to capacity as they do not get enough supplies of coaltar. Distillers who buy the coaltar and have to transport it over some distances are experiencing serious difficulties as very often it has to be filled into drums for want of tank wagons with the railways for the purpose. This method of transport is wasteful and seriously impairs the economy of coaltar distillation by these firms. An adequate number of tank wagons should be made available for transporting coaltar by the Railways.

5.3. The following tables show the capacity and production of coaltar by coke ovens and coking retorts in the country, and the quantities of benzol recovered by the coke ovens which have recovery units. The quantities of benzene etc., recovered by the rectification units, the capacity of the tar distillers in the country, the quantities treated and products recovered by them are also indicated:—

TABLE No: 25—THE CAPACITY FOR CARBONISING COAL AND RECOVERY OF COALTAR AND QUANTITIES OF COAL ACTUALLY CARBONISED AND COALTAR RECOVERED IN 1952 AND 1953

Annual installed capacity for carbonising coal by coke ovens & coking retorts in the country (tons)	Annual installed capacity for coaltar recovery (tons)	Annual installed capacity for benzol recovery (Galls)	Coal carbonised in		Coaltar recovered in		Motor benzol recovered in	
			1952	1953	1952	1953	1952	1953
	(tons)	(Galls)	(tons)	(tons)	(tons)	(tons)	(Galls)	(Galls)
36,27,400	1,05,300	18,89,000	31,61,676	29,89,461	93,926	93,194	14,81,295	13,24,783

TABLE No: 26—THE CAPACITY OF RECTIFICATION UNITS AND QUANTITIES OF BENZENE TOLUENE AND SOLVENT NAPHTHA RECOVERED IN 1952 AND 1953

Installed Capacity in the country			Quantities recovered				
Benzene (Gals)	Toluene (Gals)	Solvent naphtha (Gals)	Benzene 1952 (Galls)	1953 (Galls)	Toluene 1952 (Galls)	1953 (Galls)	Solvent naphtha 1952 (Galls)
88,500	3,39,500	N.A.	38,826	49,999	2,91,707	2,72,123	1,10,646
							1,11,322

TABLE No: 27—THE CAPACITY OF COALTAR DISTILLERS AND QUANTITIES OF COALTAR TREATED IN 1952 AND 1953 AND PRODUCTS RECOVERED

Capacity for distilling coaltar (Tons)	Coaltar distilled		Light cresote oil recovered in		Naphthalene recovered in	
	1952 (Tons)	1953 (Tons)	1952 (Galls)	1953 (Galls)	1952 (Tons)	1953 (Tons)
72,100	59,720	52,699	1,49,555	2,00,560	667	586

5.4. To improve the production of coaltar products, the recovery of benzol in the coke ovens operated in the country, should be made compulsory unless the units are too small for its economical recovery.

5.4.1. At present, since benzol is being used by the petrol companies for mixing with petrol for making motor fuel, an excise duty, equivalent to that charged on petrol is being levied on this product. The coke oven plants which use benzol recovered in their rectification units for the production of benzene etc., have therefore also to pay the same duty and claim a rebate for the quantities consumed for this purpose. This procedure involves many difficulties and kills all incentive to operate their rectification units to capacity. The coke oven plants which have no rectification units therefore do not recover normally more benzol than what is actually required by the petrol companies. In order to create an incentive for coke oven plants to recover more benzol, than that required by the petrol companies and make it available for the recovery of benzene and toluene, the excise duty levied on benzol should be removed irrespective of the purpose for which it is used.

5.4.2. The existing practice of burning coaltar by the Steel Companies in their open hearth furnaces leads to a waste of an important national resource and should be stopped till such time as enough coaltar is available for purposes of distillation. Mere considerations of cost should not be allowed to stand in the way. Once sufficient quantities of coaltar are made available to the distillers and markets for the products derived from them are developed, the steel companies are bound to get more remunerative prices for coaltar.

5.5. Out of the 23 million tons of coal mined annually in the country, only about 3 to 4 million tons of coal are being carbonised by the byproduct coke ovens. If all the benzol and coaltar that are likely to be formed during this process are recovered and worked for its various ingredients, substantial quantities of coaltar products can be obtained which will be of help in establishing a coaltar products industry in the country.

5.6. New coke ovens are being installed at the Sindri Fertilizers Factory, which are expected to produce 500 to 600 tons of coke per day and yield 36 tons of coaltar per day. This will add another 12,000 tons of coaltar per annum to the existing production and would be of a better quality than that obtained from coke ovens operated for producing metallurgical coke. These coke oven plants are also being provided with the necessary unit for the recovery of benzol and its rectification. The quantities that are expected from these coke ovens are:—

	Tons/annum
Motor benzol . . . . .	2,100
Solvent naphtha . . . . .	140
<i>Or alternatively</i>	
Benzene . . . . .	1,750
Toluene . . . . .	340
Xylene . . . . .	105
Solvent naphtha . . . . .	105

With the installation of the new State owned Iron and Steel Plant in Orissa and expansion of Tata Iron and Steel Co., Jamshedpur under contemplation, further quantities of coal will be carbonised for the production of metallurgical coke and this will add substantially to the production of benzol and coaltar. With these developments and by conserving the existing resources we feel that sufficient quantities of the starting materials will be available for establishing a coaltar products industry in the country.

5.7. The requirements of coaltar products by the pharmaceutical industry should be evaluated on the basis of the co-ordinated development programmes of the pharmaceutical manufacturers during the next five years.

5.7.1. As the demands of the pharmaceutical industry alone may not be large enough for an economical production of the coaltar products to be possible, similar estimates of the requirements of coaltar products by the Plastic and Dyestuff industries which are also in their early stages of development, should be made and correlated with those of the pharmaceutical industry. This will create sufficient demand for taking up of an economical production of the coaltar products.

5.7.2. By co-ordinating the requirements of the pharmaceutical industry with those of the Dyestuffs and Plastics industries, a long term programme of manufacture of coaltar chemicals in the country should be drawn up.

5.7.3. The Government should take up the manufacture of essential coaltar products if sufficient response from the private sector is not forthcoming.

5.8. To give an idea of the quantities of the coaltar chemicals and intermediates that will be required by the pharmaceutical industry, we have worked out in the flow-sheets in Appendix No. 8, the quantities of the basic chemicals required for the production of 31 important synthetic drugs based on their estimated demands in the country. Tables showing the estimated demand of the 31 essential chemicals worked out in the flow-sheets with the total quantities of raw materials required for their production are given below:—

**TABLE NO. 28—THE ESTIMATES OF ANNUAL DEMAND OF ESSENTIAL DRUGS WORKED OUT IN THE FLOW-SHEETS GIVEN IN (APPENDIX NO. 8)**

---

**SULPHA DRUGS :**

1. Sulphathiazole . . . . .	1,80,000 lbs.
2. Sulphadiazine . . . . .	1,50,000 „
3. Sulphaguanidine . . . . .	50,000 „

**SYNTHETIC ANTIMALARIALS :**

4. Paludrine . . . . .	30,000 „
5. Chloroquin . . . . .	30,000 „

**SYNTHETIC VITAMINS :**

6. Nicotinic acid and amide . . . . .	1,200 „
---------------------------------------	---------

**HYPNOTICS :**

7. Luminal Barbituarates	. . . . .	2,280 kg. (5,000 lbs. approx).
8. Chloral Hydrate	. . . . .	35,000 lbs.

**ANAESTHETICS :**

9. Ether (B.P. and anaesthetic)	. . . . .	3,40,000 "
10. Chloroform	. . . . .	1,00,000 "
11. Ethyl Chloride	. . . . .	50,000 "

**ARSENICALS :**

12. Neorsphenamine	. . . . .	} 2,500 "
13. Sulpharsphenamine	. . . . .	

**ANTI-LEPROSY :**

14. Dapsone (DADPS)	. . . . .	10,000 "
---------------------	-----------	----------

**ANTI-TUBERCULAR :**

15. Para-amino-salicylic Acid (PAS)	. . . . .	1,05,000 "
16. Isonicotinic Acid Hydrazide (INH)	. . . . .	20,900 "

**ALKALOIDS\*:**

17. Ephedrine Hydrochloride	. . . . .	1,000 "
18. Emetine Hydrochloride	. . . . .	275 "
19. Codeine	. . . . .	1,000 "

**INSECTICIDES :**

20. D.D.T.	. . . . .	} 8,000 tons upto 1956 and thereafter 5,500 tons.
21. B.H.C.	. . . . .	

**OTHERS :**

22. Iodo-Chloro-oxyquinoline	. . . . .	} 30,000 lbs.
23. Di-iodo-oxyquinoline	. . . . .	
24. Nikethamide	. . . . .	12,000 "
25. Carbarsone	. . . . .	700 "
26. Aspirin	. . . . .	15,00,000 "
27. Sodium Salicylate	. . . . .	4,50,000 "
28. Chlorobutanol	. . . . .	250 "
29. Cinchophen	. . . . .	2,500 "
30. Argenti Proteinus	. . . . .	1,500 "
31. Saccharine	. . . . .	2,00,000 "



TABLE NO. 29—THE TOTAL REQUIREMENTS OF BASIC RAW MATERIALS FOR THE PRODUCTION OF ESSENTIAL CHEMICALS LISTED IN TABLE NO. 28 ABOVE

Basic raw material	Quantities required in lbs.
1. Liq. Ammonia . . . . .	2,000
2. Ammonia . . . . .	5,26,500
3. Acetone . . . . .	1,49,000
4. Arsenious oxide . . . . .	11,900
5. Arsenic pentoxide . . . . .	44,200
6. Ammonium Nitrate . . . . .	97,500
7. Ammonium Sulphate . . . . .	9,30,000
8. Acetic acid . . . . .	5,25,500
9. Acetic anhydride . . . . .	15,00,000
10. Acetophenone . . . . .	1,500
11. Alcohol	
(a) Methyl alcohol . . . . .	15,500
(b) Alcohol (abs) . . . . .	52,90,600
(c) Rectified spirit . . . . .	10,00,600
(d) Methylated spirit . . . . .	5,76,000
12. Benzene . . . . .	1,31,83,600
13. Bleaching powder . . . . .	10,24,500
14. Bromine . . . . .	1,300
15. Chlorine . . . . .	2,87,81,900
16. Caustic Soda . . . . .	39,59,100
17. Carbon di-oxide . . . . .	11,92,200
18. Chloro sulphonic acid . . . . .	46,71,000
19. Copper sulphate . . . . .	33,600
20. Calcium cyanide . . . . .	6,28,500
21. Caustic potash . . . . .	31,800
22. Chromic acid . . . . .	1,400
23. Casein . . . . .	1,400
24. Carbon-di-sulphide . . . . .	24,300
25. Chalk . . . . .	7,000
26. Calcium chloride . . . . .	50,200
27. Common salt . . . . .	2,13,000
28. Dowtherm 'A' . . . . .	15,000
29. Diethylamine ethanol . . . . .	30,000
30. Diethylaniline . . . . .	530
31. Diethyl oxalate . . . . .	18,750
32. Diethylamine hydrochloride . . . . .	10,600
33. Ethoxy methylene . . . . .	45,000
34. Ephedra . . . . .	2,28,000
35. Ether . . . . .	89,300
36. Ethyl iodide . . . . .	10,000
37. Ferric chloride . . . . .	900
38. Formaldehyde . . . . .	1,600
39. Gamma-picoline . . . . .	2,300

Basic raw material	Quantities required in lbs.
40. Gelatine . . . . .	5,650
41. Glycerine . . . . .	79,500
42. Hydrochloric acid . . . . .	7,22,200
43. Hydrogen . . . . .	2,400
44. Hydrobromic acid . . . . .	700
45. (a) Iron filings . . . . .	12,38,000
(b) Iron powder . . . . .	18,750
46. Iodine . . . . .	25,500
47. Apecac root . . . . .	13,800
48. Isopropyl amine . . . . .	27,000
49. Indigo . . . . .	2,325
50. Pot. iodide . . . . .	30,000
51. Magnesium chloride . . . . .	9,100
52. Magnesium sulphate . . . . .	2,500
53. Morphine . . . . .	1,140
54. Methyl benzene sulphonate . . . . .	750
55. Malic acid . . . . .	6,75,000
56. Nitric acid . . . . .	4,70,500
57. Pot. dichromate . . . . .	32,000
58. Petroleum Naphtha . . . . .	15,000 gallons.
59. Phenol . . . . .	4,500
60. Phosphorous oxychloride . . . . .	13,35,000
61. Phosphoric acid . . . . .	1,500
62. Pot. bi-carbonate . . . . .	4,62,000
63. Paraffin Durum . . . . .	9,000
64. Pot. Cyanide . . . . .	1,600
65. Pot. permanganate . . . . .	6,19,100
66. Pyridine . . . . .	22,500
67. Pot hydroxide . . . . .	16,000
68. Quick lime . . . . .	60,500
69. Roney Nickel . . . . .	300
70. Sulphuric acid . . . . .	7,25,44,000
71. Soda Ash . . . . .	3,36,550
72. Sodium aceto-acetic ester . . . . .	39,000
73. Sulphuryl chloride . . . . .	2,700
74. Sodium Nitrate . . . . .	7,500
75. Sodium sulphide . . . . .	51,600
76. Sodium Nitrite . . . . .	18,000
77. Sodium hydrosulphite . . . . .	76,600
78. Sodium bi-sulphite . . . . .	1,000
79. Sodium (Metal) . . . . .	6,000
80. Silver Nitrate . . . . .	200
81. Toluene . . . . .	13,61,500
82. Urea . . . . .	26,400
83. Thiourea . . . . .	1,38,600
84. Thionyl Chloride . . . . .	26,400
85. Venyl acetate . . . . .	1,49,400

5.9. We have given in the Chapter under Demand and Production, a list of items, whose production, we consider, should be encouraged in the country. The actual quantities of basic chemicals required by the industry will exceed considerably the quantities indicated in the above statement, if the development of all the items given therein is taken up. After a co-ordinated development programme of different manufacturers that we have recommended earlier is finalised, an estimate on the above lines of the actual quantities of the coaltar and other fine chemicals required for the development of the industry, should be worked out. To start with, the demands of the pharmaceutical industry may not be large enough to justify the production of some of these basic chemicals and intermediates in the country. Since some of them also form the starting materials or intermediates of the dyestuffs and plastics industries which are also in their early stages of development, their demands should also be evaluated on similar lines based on their development programmes. These demands should be correlated with those of the pharmaceutical industry to see wherein production of these chemicals could be economically taken up in the country.

## 6. Animal Glands and Organs:

6.1. Hormones have increasingly come into use during recent years in modern medicine. Except in a few cases, where such hormones have been synthesised, their main source are glands and organs of slaughtered animals whose active principles they form. The most important among them are the anti-anaemic factors obtained from liver, insulin from the pancreas, pituitarine from the anterior and posterior lobes of the pituitary, and valuable enzymes like pepsin, trypsin, pancreatine etc., from the stomach pancreas and linings. These have to be removed from the carcass soon after the animals have been slaughtered and stored at low temperatures to prevent their deterioration if they have to be used for the extraction of their active principles. The hormones in the smaller glands like suprarenal, ovaries, thyroid, parathyroid, thymus and pituitary deteriorate so rapidly that within half an hour of slaughtering of the animal, more than three-fourths of the active principles would have been rendered useless. None of the slaughter houses in the country offer any facilities for such rapid collection or their proper storage. Normally in these slaughter houses more than an hour lapses between slaughtering, flaying and opening of an animal. Therefore, the hormones from these small glands are invariably lost. Some of the organs such as the liver, spleen, heart, testes, etc., which do not deteriorate so rapidly, however, are being collected by the pharmaceutical concerns from the slaughter houses in big cities, within a reasonable time after the animals are slaughtered, and carried to their factories and preserved in cold storage. Even in these cases the slaughter houses afford no facilities and what little is being collected and utilised is due entirely to the efforts of the pharmaceutical manufacturers who most often have to coerce the butchers to part with the glands before they deteriorate. To increase their weight they are often soaked in water, and mixed up with connective tissues and fat and this common practice hastens their deterioration.

6.1.1. The following table shows the number of slaughter houses in the country, the authorities under whose supervision they work and the different types of animals slaughtered in them:—

TABLE NO. 30— THE NUMBER OF SLAUGHTER HOUSES IN THE DIFFERENT STATES AND DIFFERENT TYPES OF ANIMALS SLAUGHTERED PER DAY

States	No. of Slaughter Houses	Administered by	Animals slaughtered per day			
			Sheep & Goat	Cows & Buffs	Other animals	Total
<b>PART 'A' STATES :</b>						
1. Assam . .	26	Municipalities .	N.A.	N.A.	N.A.	N.A.
2. Bihar . .	90	Do.	1,225	220	49	1,494
3. Bombay . .	423	72 by Municipalities and 351 by public.	7,000	N.A.	500	7,500
4. Madhya Pradesh .	123	Municipalities	1,086	24	56	1,166
5. Madras . .	213	Do.	6,484	143	33	6,660
6. Orissa . .	15	Do.	78	6	129	213
7. Punjab . .	83	Do.	842	N.A.	3	845
8. Uttar Pradesh .	109	Do.	784	203	36	1,023
9. West Bengal . .	29	Do.	1,775	531	89	2,395
<b>PART 'B' STATES :</b>						
10. Hyderabad . .	7	Do.	960	92	N.A.	1,052
11. Madhya Bharat .	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
12. Mysore . .	15	N.A.	N.A.	N.A.	N.A.	1417
13. PEPSU . .	45	Municipalities	274	N.A.	N.A.	274
14. Rajasthan . .	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
15. Saurashtra . .	22	Municipalities	350	20	..	370
16. Travancore-Cochin	N.A.	N.A.	N.A.	N.A.	N.A.	N. A2.
<b>PART 'C' STATES :</b>						
17. Ajmer . .	3	Municipalities	300	2	N.A.	302
18. Bhopal . .	3	Do.	54	9	N.A.	63
19. Bilaspur . .	N.A.	Do.	3	N.A.	N.A.	3
20. Coorg . .	20	Do.	94	17	4	115
21. Delhi . .	4	Do.	1,200	50	5	1,255
22. Himachal Pradesh	4	Do.	26	N.A.	1	27
23. Kutch . .	5	Do.	100	N.A.	N.A.	100
24. Manipur . .	Nil	..	..	..	..	..
25. Tripura . .	1	Municipalities	7	N.A.	N.A.	7
26. Vindhya Pradesh .	3	Do.	70	N.A.	N.A.	70
<b>OTHER STATES :</b>						
27. Jammu & Kashmir	35	Do.	197	Nil	..	197
TOTAL . .	1,278	..	22,909	1,317	905	26,548

6.2. The manufacture of hormones and glandular products in the country is insignificant when compared to the demand and this is mainly due to the virtual absence of facilities for collection and storage of glands. Modern slaughter houses with facilities for proper collection and storage of glands and organs should be established to start with, in cities such as Bombay, Madras, Calcutta and Delhi.

6.2.1. The collection and preservation of these glands should be supervised by qualified personnel and, as at present, not left to the butchers, who have no knowledge of the actual glands required and the methods of extracting and preserving them.

6.2.2. The Report of the Committee for the improvement of Slaughter Houses under the chairmanship of Shri R. P. Masani, gives in detail the existing conditions of slaughter houses in the Bombay State, which is more or less true of slaughter houses throughout the country. The recommendations made by the Committee for their improvement particularly with reference to the collection and storage of organs and glands of slaughtered animals should be implemented in all the slaughter houses in principal towns of the country. We have given a summary of the recommendations of this Committee in Appendix No. 9.

#### (b) PACKING MATERIALS OF THE INDUSTRY

##### 1. Glass Containers:

1.1. The total production of glass and glassware in this country is about 92,350 tons per annum of which containers alone amount to nearly 60,000 tons. These containers are supplied to pharmaceutical, chemical and food processing industries, ink manufacturers, aerated water manufacturers etc. The demand by the pharmaceutical industry of bottles and other glass containers is the largest. A large number of glass factories appear therefore to have been put up in the States of Bombay and Bengal which are also the major centres of production of pharmaceuticals. The following table shows the distribution of glass factories in the different States with their installed capacity and production:—

TABLE NO. 31—THE NUMBER OF GLASS FACTORIES STATE-WISE WITH THEIR INSTALLED CAPACITY AND PRODUCTION IN THE YEAR 1952

State	Number of factories	Annual installed capacity in tons	Production (1952) in tons
Bengal . . . . .	30	63,600	34,050
Bombay . . . . .	22	44,400	21,242
U.P. . . . .	21	36,960	14,654
Bihar . . . . .	8	35,300	5,634
Madras . . . . .	8	6,850	2,662
Madhya Pradesh . . . . .	5	4,220	2,824
Punjab & PEPSU . . . . .	4	4,140	3,331

State	Number of factories	Annual installed capacity in tons	Production (1952) in tons
Delhi . . . . .	2	1,200	600
Rajasthan . . . . .	2	900	196
Hyderabad . . . . .	2	3,980	1,908
Saurashtra . . . . .	1	360	243
Mysore . . . . .	1	720	503
Travancore . . . . .	1	600	418
Orissa . . . . .	1	3,600	3,970
Madhya Bharat . . . . .	1	1,800	115
TOTAL . . . . .	109	2,08,630	92,350

The quality of bottles, particularly those supplied to the pharmaceutical industry, and to the profession for the dispensing of drugs and medicines, are far from satisfactory.

1.2. The different products of the pharmaceutical industry packed in such glass containers vary widely in their physical and chemical properties. They comprise of powders, tablets, granules, ointments, syrups and liquids. The stability of the pharmaceutical products when packed in glass containers depends to a large extent on the nature and characteristics of the glass of the container. The quality of bottles and other glass containers supplied to the pharmaceutical industry and for dispensing drugs and medicines has therefore got to conform to varying requirements depending on the nature of products to be packed in them. The glass manufacturers have not realised that there cannot be an all-purpose container and the composition of the glass should be adjusted to meet the different requirements of the industry. In most cases a constant batch of raw materials goes into the use for making tumblers, chimneys and bottles. Since the glass used gives an alkaline reaction, quite often the pharmaceuticals when stored in them get decomposed by reacting with the glass surface. Also the rough surface of the glass containers are sometimes responsible for starting de-composition of certain products packed in them. In addition to these defects in the quality of glass used, the following mechanical defects in their moulding commonly noticed also create difficulties in their use in the pharmaceutical industry:—

- (i) Containers are irregular in shape, do not have a smooth surface and are not quite transparent due to the presence of air bubbles, unmelted sand etc. and hence do not present an elegant appearance;
- (ii) They have uneven walls and varying thickness at the bottom which decreases the filling capacity of the containers besides reducing their resistance to thermal and mechanical shocks. The thick walls also increase their weight and indirectly raise the cost of transport of the pharmaceuticals;

- (iii) Due to improper moulding the neck is not uniform in diameter and stoppers and cork of a specified standard size do not fit tight into the mouth of the container. Similar defects are found in tablet tubes. Plastic caps when used do not fit tight on to them;
- (iv) In the case of containers with screw caps, the size of the threaded portion is not quite often vertical and the threads are not uniform. The face of the neck of bottle on which the washer of the cap is supposed to sit and make a leak-proof seal is not always horizontal and in level and lead to leakage and consequent contamination. At the site where the two sections of the mould come in contact a ridge is found running straight up to the face of the neck and this edge is very often so sharp that it not only breaks the screw-cap but very often causes injury while handling the bottles; and
- (v) The glassware are not properly annealed and they break into pieces with little or no shock which leads to a total loss of the contents.

1.3. The glass manufacturers feel that, although some of the defects were due to inherent difficulties, the most serious of them was the demand of consumers (in this case the pharmaceutical manufacturers) on cheap goods, to meet which they have to reduce the quality of their products. A question of cheap goods leads to a vicious circle and here the responsibility of the consumers cannot be overlooked. The glass manufacturers contend that it is the consumer, who insists upon the supply of bottles with a lesser capacity than what is apparent by manipulating the thickness of the glass, for example a 4 oz. bottle will actually hold only about 3 oz.

1.3.1. The containers are very important for the pharmaceutical manufacturers. They must, therefore, insist on quality and not on a low price. They should demand goods of standard specifications and decline to purchase cheap ones that do not conform to them. If this measure is adopted by chemical manufacturers, it will eliminate the cheap manufacturers whose criteria is based only on the price factor and will raise the level of the glass industry and also the reputation of the chemical manufacturers in the eyes of the public. The manufacturers of glass bottles on their part should try to specialise in particular types of containers instead of being engaged in making all types of containers. This will enable them to meet the special requirements of any industry. The following extract from the Third Quarterly Report for 1952 of the Birmingham City Analyst in the U.K., will show the care and attention that is necessary in choosing containers for the Pharmaceuticals.

"A sample of an eye-lotion, on the label of which was a declaration of the presence of 0.25 per cent. borax and 0.125 per cent., zinc sulphate, was analysed. Inspection of the bottle showed that the sides and bottom were covered with an adherent layer of what proved to be zinc oxyborate and analysis of the mixture proved it to contain 0.19 per cent. borax and only 0.045 per cent. zinc sulphate,

the remainder of these two salts originally present having been precipitated. The presence of solid particles in an eye-lotion was obviously objectionable and the vendor was asked for an explanation. The actual manufacturers reported to him that none of this particular brand had been delivered within the last two years, and that, therefore, it would appear to be a bottle the contents of which were made to an earlier formula and had, as one might expect, deteriorated over the period in question. The preparation was withdrawn from sale."

"Another sample of eye-lotion was described on a label as containing, among other things,  $1\frac{1}{3}$  grains of cocaine hydrochloride per 4 fl. oz. The amount actually found was only 0.2 grain, a deficiency of 85 per cent. In addition, the formula given ended with the words "water to 4 fluid ounces", but the contents of the bottle amounted to 3 fl. oz. only. This is a contravention of Section 11 (2) of the Pharmacy and Medicines Act, 1941, which defines the phrase "appropriate quantitative particulars" of the constituents of such a mixture as meaning the approximate quantity of each of the ingredients contained in the article sold or supplied. Therefore, states the Analyst, either the amounts of ingredient contained in three fluid ounces should have been given or else the bottle should have been of a capacity of four fluid ounces."

1.3.2. All the big consumers of glass products *viz.*, chemical manufacturers, food processing companies and condiment manufacturers are unanimous in their complaint that the bottles supplied to them are not of standard quality and that after some time, the contents gradually deteriorate due to the chemical reaction with the surface of the walls of the container. In order to avoid this, there is need for a clear understanding between the suppliers and consumers regarding their particular requirements. The supply of a particular type of container could be entrusted to a particular manufacturer or group of manufacturers depending upon the facilities they possess for the purpose, who would then specialise in the production of this particular type of container instead of producing all types. This would ensure not only quality of production and uniformity of supply but would even lower the cost of production.

1.3.3. No single glass container could successfully satisfy the requirements of all industries owing to the varying nature of the products to be filled in them. We were glad to note that one manufacturer in Baroda had a complete automatic unit and was producing bottles and vials mainly for the pharmaceutical industry taking the necessary precautions to satisfy the actual requirements of the customers. We also understand that steps have already been taken by another manufacturer in Benaras to instal a complete automatic unit and several more were under contemplation in the country. These units which can maintain complete control on the composition of the glass and the final products turned out and maintain supply of uniform type of glass containers, can be entrusted with the manufacture of special types of bottles required by the pharmaceutical industry.



1.4. *Ampoules, Vials etc.*—The other types of glassware required in the pharmaceutical industry such as ampoules, vials, tablet-tubes etc., are also produced in the country either as a subsidiary of the pharmaceutical industry or as a cottage industry. The starting material for this purpose is the glass-tubing produced by several of the glass factories. The composition of glass commonly used for the tubing is not neutral or even uniform in quality with the result the ampoules made out of them show varying alkalinity. This decomposes some of the parenteral products filled in the ampoules. Also as this glass tubing is usually hand-drawn, the diameter of the glass-tube varies as much as 20 per cent. and the thickness of the wall of the tubing is not uniform. Ampoules and vials made from them, therefore, have the same defects and cannot be used in automatic filling and sealing machines. As these vials and ampoules are in turn blown by hand, the neck is often off the central axis and this adds to the difficulty of using them in automatic filling and sealing machines. There is only one glass factory in India situated in the State of Bihar making machine-drawn glass tubing. A firm in Calcutta is using this glass-tubing, as also imported glass tubing and turning out machine made ampoules. It is reported that their products are quite suitable for use in automatic filling and sealing machines. A factory in Calcutta is also producing neutral glass and chemically resistant glass-tubings. But here again, the tubes are hand-drawn and probably the ampoules and vials made out of them create the same difficulties for use in automatic filling and sealing machines. The production of more machine-made tubing and ampoules should be encouraged if more automatic filling and sealing is to be adopted by the pharmaceutical manufacturers. The production of neutral glass tubing and its use in ampoule making should be encouraged.

1.5. *Standardisation.*—The Central Glass and Ceramic Institute at Calcutta and the Indian Standards Institution at Delhi could help in solving some of these problems by laying down standards for the quality of the glass containers required for different purposes. Certain amount of work has been done on the study of Indian glass containers used in the pharmaceutical industry by Doctors Basu and Bhattacharya in the Bengal Immunity Research Institute at Calcutta and this work could well be made the starting point for laying down the standards of quality. It may not be long before glass containers are replaced by plastic containers. It is, therefore, desirable that standards for such alternative containers should also be drawn up.

1.5.1. There is also a tendency among the Indian manufacturers to use fancy shaped containers for packing medicines for internal administration, which is not desirable. Actually a marked distinction in colour and shape between bottles used for packing medicines meant for internal use and those that are not, is necessary. Normally, for packing medicines not intended for internal administration, bottles of a deep blue or green colour and of hexagonal shape are used in the U.K., so that they could be identified both by their sight and feel. This could be adopted in this country also and if the usual hexagonal shape is considered difficult and costly to make, bottles shaped like 'Ribbed oval' could be used instead. The Standards Institution should also take up this matter while drawing standards for bottles meant for packing different products.

1.5.2. The Weights and Measures Act is already in force in various States. It should be enforced strictly in all States and the practice of dispensing in bottles of lower capacity than that stated should be penalised.

1.5.3. Standards have been laid down for dispensing measures by the British Standards Institution detailed below for pharmaceutical purposes:—

B.S. No. 1921—Dispensing Measures for Pharmaceutical purposes (Imperial Units).

B.S. No. 1952—Dispensing Measures for Pharmaceutical purposes (Metric Units).

B.S. No. 604—Graduated Measures (Cylinders).

B.S. No. 795—(Ampoules).

These standards which are both in Metric and Imperial Units should be adopted, in respect of containers used by dispensing chemists. While there is no British standard specification, tests have been laid down in the B.P. as well as U.S.P. for the quality of the material used. In regard to the capacity and the variation that is allowed, the Glass Manufacturers Federation of England have opined as under:—

“To begin with, no single bottle must be taken as a measure in itself, and whilst I think we can say that glass containers are remarkably accurate on the average in capacity at the same time no individual bottle can be guaranteed, because it is impracticable to measure and verify each bottle which is manufactured by mass production means. The capacity of most of the glass containers is specified as a capacity to a given filling point with a plus and minus tolerance, but the capacity is assessed on the average of a number of bottles and not on individual bottles.”

“So far as medical bottles are concerned there is no standard relationship between the nominal capacity and the bulk of the medical bottles which are supplied to the following tables:—

Nominal Capacity	Capacity to the foot of the neck	Tolerance
4 oz. . . . .	4 $\frac{1}{8}$	$\frac{3}{32}$ of a fl. oz.
6 oz. . . . .	6 $\frac{3}{16}$ fl. oz.	$\frac{1}{8}$ do.
8 oz. . . . .	8 $\frac{1}{4}$ fl. oz.	$\frac{3}{16}$ do.
10 oz. . . . .	10 $\frac{5}{16}$ fl. oz.	$\frac{1}{4}$ do.
12 oz. . . . .	12 $\frac{5}{16}$ fl. oz.	$\frac{1}{4}$ do.

It will be seen that the minimum capacity in each case is slightly above the normal capacity, and this presumably has been specially arranged to allow room for shaking when the bottle is correctly filled. In the case of bottles with panels, we are told that the minimum capacity to the filling point is the nominal capacity. Tolerances for panels would be approximately the same as medicals, or perhaps slightly more because panels are more difficult to manufacture."

## 2. Cork:

2.1. Large amount of cork is required in the pharmaceutical industry mainly for use as stoppers of bottles. Its peculiar characteristics like light weight, high coefficient of friction, resilience, chemical inertness, fair impermeability, absence of taste and odour, and cheapness, make it specially suited for this purpose. It is also used because of these properties in making floats, stoppers, handles, all types of linings, sports goods etc. Cork is not produced in India but is mainly imported from Spain, Portugal and other Mediterranean countries. The import of cork into India for the last 5 years from these countries is given in the following table:—

TABLE NO. 32—IMPORTS OF CORK INTO INDIA DURING 1948-49 TO 1952-53

Period	Quantity in tons	Value in rupees
1948-49 . . . . .	1165.2	26,14,807
1949-50 . . . . .	1325.95	27,38,716
1950-51 . . . . .	1241.65	34,67,773
1951-52 . . . . .	849.6	37,00,027
1952-53 . . . . .	650.65	25,67,713

2.2. Cork commonly used is the outer bark of the cork-oak (*Quercus Suber L.* and its varieties). The outer bark has the ability to regenerate within a few years after it is stripped. The bark of the trees are stripped generally when they are 20 to 30 years' old and at 10 years' intervals thereafter until they are 100 years' old. It is reported that the highest grade of lenticellular pore-space value and a uniform quality can be obtained from the third to sixth peeling from 50 to 80 years' old plants. Apart from the production of cork, the tree yields acorns which are considered as excellent cattle food. In the U.S.A., efforts have been made to grow cork and remarkable success has been achieved in the special plantations. This has prevented the U.S.A., from being completely dependent on imports.

2.3. The Cork-oak is not found in India. But at various times the introduction of this plant appears to have been tried. It is also reported that in Kashmir cork has been produced from the trees that were planted in the State although no details of this production are

available. Other species of quercus are found at different levels of Himalayas and it is worth investigating if these could give valuable substitutes for cork in this country. Simultaneously cork-oak cultivation in suitable climatic conditions should be undertaken as in the U.S.A., to avoid complete dependence of this country on imports. This could be tried by making experimental plantations in the different States taking soil, climate and other factors into consideration.



सत्यमेव जयते

## CHAPTER IV

### DEMAND AND PRODUCTION

#### 1. General:

1.1. There is a growing demand for modern drugs in the country as people are becoming more and more conscious of recent advancements in medicine both preventive and curative. The demand is likely to increase all the more with the rise in the standard of living, and the spread of medical relief to the rural areas. The pharmaceutical and drug industry will, therefore, have to expand to meet this rapidly increasing demand.

#### 2. Essentiality of drugs:

2.1. Although the human body possesses wonderful defensive and recuperative powers, during certain occasions and for a variety of reasons, it is unable to resist bacterial invasion and other noxious agents, and return to normal health without help from external sources. In such cases, assistance is given in the form of treatment which falls into the following two categories:—

(i) General including Nursing.

(ii) Administration of Drugs.

With the first category, we are not concerned here and it will suffice to say that careful and intelligent nursing is probably the decisive factor for recovery in many cases. Drugs which come next are the chief adjuncts to proper nursing. They help to keep the disease tissues at rest, tone up the general bodily activities, soothe the patient and promote the elimination of waste and poisonous matter present in the body. Treatment with a drug which may be efficacious against one disease may be valueless against another or even harmful to the patient. It is, therefore, of vital importance to establish the correct diagnosis as soon as possible. No doctor can diagnose any bacterial disease with certainty without a bacteriological examination. The pathogenic germs are frequently indistinguishable under the microscope, almost identical in colony form, closely similar in their chemical activities and are identifiable only by delicate laboratory tests, which require time for their accurate performance. Drugs, therefore, when given under proper medical supervision, are of value; but when taken indiscriminately they are generally harmful. To enable the human being to strengthen the defences of the body and carry on the war with the invading germs and also help in other ways to restore healthy conditions of the body, a large variety of drugs is prescribed. The earlier drugs were all derived from organised structures, mainly of vegetable origin, and even at present, these are frequently used in the form of extracts and tinctures. With the isolation of the actual active principles present in the plants, and the establishment of correct relationship between their dosage and physiological effect, a group of compounds known as alkaloids and

glucosides have come into use. A study of their chemical structures has led to their synthesis and added to the list of drugs a number of synthetic substitutes and related compounds. In addition, numerous other synthetic products, which have been introduced into medicine from time to time, a large number of them made from byproducts obtained in the synthetic dye industry, have given rise to a system of treatment known as chemotherapy. Hormones extracted from glands of animals or prepared synthetically for treating glandular dysfunctions, and vitamins obtained from natural sources or synthetically prepared for treating nutritional deficiencies, have swelled the list of remedies used in modern medicine. Recently, another group of compounds produced with the help of micro-organisms—the antibiotics, has been added to the already large list of remedies. It would be impossible to give an estimate of demand for all these products and their preparations and suggest steps for their production in the country. A tentative list of essential drugs, whose production should be encouraged in the country, has however, been prepared, after consulting various medical institutions, army authorities and the members of the medical profession through their representative organisations, the Indian Medical Association and the All-India Medical Licentiates' Association and is given in Appendix No. 10. Brief notes on the different groups of essential drugs are given in the succeeding paragraphs.

**2.2. Antibiotics.**—Antibiotics are substances produced by micro-organisms which have the capacity of inhibiting the growth and even of destroying other micro-organisms. These drugs have had a profound effect on public health and since their advent has brought down mortality rates for several diseases. Numerous antibiotics have been screened but only a few of them have been found to fulfil the exacting conditions that permit of their clinical use. Among these are penicillin, streptomycin, chloramphenicol, tetracyclin, chlortetracyclin, and oxytetracyclin and erythromycin from a group of organisms known as 'actinomycetes' and polymyxins, bacitracin, subtilin and others obtained from 'Gram-positive bacilli'.

**2.2.1. Penicillin.**—Among the different types of penicillin isolated, benzyl penicillin (penicillin G) is clinically the most generally desirable at the present time. In general, penicillin is the drug of choice in the treatment of infections due to the Gram-positive organisms such as those causing tonsillitis, scarlet fever, anthrax, some types of pneumonia and diphtheria (with antitoxin) the Gram-negative organisms causing gonococcal infections, and the spirochetes of syphilis and yaws. It is ineffective against the virus infections such as influenza and poliomyelitis and some Gram-negative infections such as typhoid.

**2.2.2. Streptomycin and dihydrostreptomycin.**—These two forms of streptomycin are used primarily in the treatment of infections due to tubercle bacillus and in cases of tularemia, peritonitis and brucellosis (in combination with sulfadiazine). The greatest limiting factor in the use of streptomycin in the treatment of infectious diseases is the rapid development of bacterial resistance. Not only streptomycin-resistant but even streptomycin-dependent strains of pathogens have been reported. To delay the emergence of organisms

resistant to streptomycin, streptomycin in conjunction with p-aminosalicylic acid and/or Isonicotinic acid hydrazide has been used. Streptomycin is the only antibiotic in general use for tuberculosis. Viomycin in recent days is coming into use in the treatment of tuberculosis.

2.2.3. *Chloramphenicol*.—This is the first antibiotic to be produced synthetically on a commercial scale. The methods of manufacture comprise of both the biological and synthetic methods. It is one of the most stable antibiotics currently available. It has some activity against all the known rickettsia which cause human disease and against some virus infections. It has proved to be of great value in cases of typhoid fever. Common illness such as measles and mumps have been treated with a measurable degree of success. Urinary tract infections, dysentery and many of the tropical diseases have responded to chloramphenicol treatment. The oral route is the recommended mode of administration.

2.2.4. *Chlortetracyclin (Aureomycin)*.—Chlortetracyclin which is a broad spectrum antibiotic is produced by submerged aerobic fermentation. It is a stable preparation which maintains its potency in the dried state at least upto 6 months. It has been used successfully in the treatment of brucellosis, rickettsial infections, tularemia and certain types of virus pneumonia. It has been used as a prophylactic measure in connection with certain surgical procedures and in cases of influenza to arrest complications due to secondary infections.

2.2.5. *Oxytetracyclin (Terramycin)*.—This is a wide spectrum antibiotic which is produced by the aerobic submerged fermentation process. Terramycin is effective against a great variety of micro-organisms including many of the gram-positive and gram-negative bacteria, the rickettsia, and certain viruses. It has been used successfully in the treatment of certain types of pneumonia streptococcal and staphylococcal infections and urinary tract infections.

2.2.6. *Tetracyclin*.—It is similar in action to the above except that it does not produce any gastro-intestinal disturbances and hence better tolerated.

2.2.7. *Erythromycin*.—This antibiotic is active against gram-positive organisms especially the staphylococci. It is claimed that it has action only on the infecting organisms and has no action on the normal intestinal bacterial flora.

2.2.8. *Bacitracin*.—Commercially this antibiotic is produced by means of a submerged aerobic fermentation process. The antibacterial properties of bacitracin are in general quite similar to those of penicillin but it is used mainly topically as it is too toxic to be used systemically. Bacterial resistance to this antibiotic does not readily develop and allergic reactions are quite uncommon. This freedom from allergic response has given it importance as an antibiotic. Furuncles, Carbuncles, Styes and impetigo are treated successfully by topical application.

2.2.9. The other antibiotics, tyrothrocine, tyrocidine, gramicidin and subtilin are also reported to be too toxic for systemic use but have limited use for topical application.

2.2.10. The role of antibiotics is not limited to medical uses alone. The use of antibiotics in canning of foods has gained great importance. It permits sterilisation at lower temperatures, thereby preserving vitamin content of the food and its natural flavour. Some of the antibiotics also act as growth stimulants and are used in poultry, piggery etc., for this purpose.

2.3. *Sulphonamides*.—The appearance of sulphonamides has limited the field of serotherapy. Sera and antitoxins of several types like antipneumonia, antimeningococci and antidysentery have been mostly replaced. Sulphonamides act effectively and quickly against bacterial pneumonia, streptococcal infections, dysentery and meningitis. They are not without their drawbacks. Sulphonamides have caused cyanosis in patients sensitive to them. The tendency of the unabsorbed drug to crystallise in the kidneys varies according to the sulphonamide employed. Large quantities of fluids will therefore have to be administered during treatment. In recent years the use of a mixture of two or three sulphonamides instead of one single compound has come into vogue. Each constituent of the mixture is thereby employed in smaller dosage than would be required were it used alone. Each exerts its own particular chemotherapeutic effect and under these conditions of administration each retains its solubility in the kidneys.

2.3.1. The antibiotics penicillin and chloramphenicol are beginning to compete with the sulphonamides. At the same time combinations of sulphonamides with antibiotics are reported to produce better results than can be obtained with either alone. In pneumococcal pneumonia, combinations of penicillin and sulphadiazine, and in meningitis combination of streptomycin and sulphadiazine have been used with better results.

2.4. *Antimalarials*.—Among the synthetic antimalarials chloroquine and its salts are in the forefront today for the treatment of malaria. They are reported to be effecting, in most cases clinical cure and disappearance of parasites within two days. But their high cost is coming in the way of their widespread use. Mepacrine seems to have lost its popularity due to its occasional untoward manifestations although it is the cheapest antimalarial at present. Proguanil which is the next cheap drug has also some drawbacks as recently recognised and reported. For mass treatment of malaria where efficacy and cheapness are both important considerations, treatment with quinine appears to be still preferred.

2.5. *Vitamins*.—Vitamins are organic substances, normally present in minute quantities in certain foodstuffs, the absence of which in the diet leads to in case of certain vitamins, well-defined morbid States. Little was known about these vitamins till a few years ago beyond the fact that abnormal diets containing less than the body's requirements of them, cause diseases. At present 15 of these essential food factors are known to exist and almost all of them have been synthesised. Synthetic vitamins, and the vitamin concentrates derived from natural sources, are both produced commercially and marketed. They have helped to cure several troublesome human and animal ailments, fortify diets deficient in them, and even sometimes helped people to omit foodstuffs that they dislike from their diets.



2.5.1. The older so-called natural vitamins—Vitamin 'A' and 'D' are found in fish liver oils and are used in the treatment of rickets, especially in children, for the development of proper teeth, for treatment of night blindness, and for building up resistance to infections. The concentrates of these vitamins are generally obtained from fish liver oils. In India, Shark Liver Oil which is rich in vitamin 'A' is used as its source.

2.5.2. Ascorbic acid (Vitamin C) is used in the treatment and prevention of scurvy, some types of dental caries and other disorders. It was the first vitamin to be synthesised on a commercial scale. It is available in the market in various pharmaceutical forms and is used in beverages, confectionery and certain special foods. This vitamin is produced in large quantities, as much as 80 to 100 tons per annum in America. The natural ascorbic acid was first made commercially available in 1934 and was sold at about \$ 213 per oz. in the U.S.A. but since the synthetic ascorbic acid has come into the market, its price has fallen down to \$ 1.65 per oz.

2.5.3. The 'B' group of vitamins which collectively constitute the B complex consist mainly of the following:—Thiamine ( $B_1$ ); Nicotinic acid; Riboflavin ( $B_2$ ); Pyridoxine ( $B_6$ ); Pantothenic acid; folic acid; cyanocobalamin ( $B_{12}$ ). Thiamine is used in the prevention and treatment of beriberi, lack of appetite in children and for neuritis of various types. It is available in various pharmaceutical forms as well as in medicinal foods. It is used in countries like America for the enrichment of flour, each pound of flour containing not less than 1.66 mg. of thiamine. In 1935, when this vitamin derived from natural sources first became available, it cost about \$ 300 per gm. in America. In 1937, when the synthetic vitamin was first sold, the price was \$ 7.5 per gm. Its price continued to drop; in 1942, it was \$ 0.53 only per gm. Nicotinic acid or niacin which is used in the cure and prevention of pellagra, is available in the market in various pharmaceutical forms, sometimes in combinations with other vitamins. It is also used for enriching flour along with thiamine. Each pound of enriched flour containing not less than 6 mg. of niacin. The price of this vitamin which was \$ 35 per lb. in 1937 in America dropped to \$ 6.5 per lb. by 1942. Riboflavin is used in the treatment of certain fissures of the lips, and Keratitis, a type of inflammation of the eyes. It is available in pharmaceutical preparations and in medicinal foods. This is also being used in the enrichment of flour, 1.2 mg. of riboflavin being used for one pound of flour. In the case of riboflavin also, the bulk price has fallen considerably even from the time when the synthetic riboflavin in bulk was first made available in 1938 at \$17.50 per gm. in America. In 1942 its price was only \$ 1.25 per gm. The uses of vitamins pyridoxine (Vitamin  $B_6$ ) and Pantothenic acid are not so well defined. There are indications that pyridoxine may be of value in the treatment of certain muscular rigidities, paralysis agitans and perhaps for other conditions. This vitamin is used in large quantities, and produced synthetically since 1939. Its price has fallen from \$ 12 per gm. in 1939 to \$ 3 per gm. in 1942. Pantothenic acid and its calcium salt have gained great interest because of their reported properties of curing and preventing white and grey hair and burning feet syndrome. They are being used in some parts of America for enriching milk. Pantothenic acid and calcium pantothenate are available in various pharmaceutical forms. In this case

too, their price has fallen from \$ 2.5 per gm. in 1940 to \$ 0.5 in 1942. Folic acid is of great value in the treatment of megaloblastic anaemias and of considerable interest in the treatment of tropical sprue. It is equally effective both orally and parenterally and has since been synthesised. Its chemical name being pteryl glutamic acid. Cynacbolamin has been recognised as the factor present in the liver extract and responsible for bringing about an increase in the haemoglobin content of the blood of patients suffering from pernicious anaemia. As such this vitamin is used for the standardisation of the potency of liver extract. It is produced commercially from the concentrates of the streptomycin liquor and also synthetically in crystalline form. It is available in various pharmaceutical forms. The entire B group of vitamins has come to the forefront as compulsory adjuncts in the treatment of diseases with wide spectrum antibiotics.

2.5.4. Two fat soluble vitamins have been synthesised—one of these vitamin 'K' is generally used in two forms:—

- (i) as vitamin  $K_1$ ; and
- (ii) as 2-Methyl-1, 4-naphthoquinone.

Both these compounds decrease the clotting time of the blood and are used in patients before operations, particularly in people suffering from jaundice and also at child birth. The other synthetic fat soluble vitamin is alpha-tocopherol (vitamin E). It is essential for proper reproduction in rats but its value in human beings is quite uncertain. It may be of value in the correction of human sterility and in the treatment of certain neuro-muscular disorders and certain cardiac dysfunctions.

2.5.5. During recent years, the scope of the use of vitamins has been widening. In the industry, vitamin 'A' is being used for its beneficial effects on the eyesight of workers in colours and exact dimensions. Vitamin 'C' is being used to prevent rancidity in fatty emulsions like butter and mayonnaise. Vitamin  $B_1$  has very wide applications. Crops irrigated with water to which additions of minute quantities of vitamin  $B_1$  have been made grow luxuriously. Injections of this vitamin in its pure synthetic form have been found to be a powerful remedy for certain types of nervous tics. Recent researches have suggested that vitamin  $B_1$  is a useful alleviative, if not an actual preventive of serum sickness which often follows second injections of antitetanic and other sera.

2.6. *Endocrines*.—Insulin, the hormone normally secreted by the pancreas and necessary to control the storage and liberation of carbohydrate by oxidation of which all the energy needed for bodily activity is liberated, has to be supplied from external sources in the case of diabetic patients. Since the days it was first commercially made available, much work has been done to modify it, so as to prolong its action on the body after injection with the object of controlling the level of blood sugar in patients with diabetes mellitus by a single daily injection. The steps towards the achievement of this objective have resulted in protamine zinc insulin, globin insulin, insulin N.P.H. and protamine zinc suspension (Insulin lente).

2.6.1. Thyroxine is another important hormone controlling human metabolism. It is secreted in the thyroid gland and stimulates the oxidation of carbohydrates, fats and non-nitrogenous part of the proteins. It is now being produced synthetically for clinical use.

2.6.2. Adrenaline is widely used clinically for its vasoconstrictor properties. The adrenocorticotrophic hormone (A.C.T.H.) from the pituitary and cortisone from the suprarenal have both assumed great importance in therapeutics. The synthesis of cortisone, especially starting from sterols obtained from vegetable sources has made possible the synthesis of this hormone on a commercial scale.

2.7. *Haematinics*.—The discovery of the effectiveness of raw liver in pernicious anaemia has registered another significant advance in medicine. The preparation of solutions for injections in which the clinically active material is concentrated has made its use widespread. The product is being increasingly produced within this country.

2.8. *Anticoagulants*.—In recent years, there has been an increasing recognition of the value of anticoagulants in the therapeutic control of thrombophlebitis and relative conditions. Heparin which is one of them is produced from oxlung. It is used in solution parenterally. The other anticoagulants such as dicoumarol, are produced synthetically and administered orally.

2.9. *Anaesthetics and analgesics*.—These drugs play an important part in the alleviation of human suffering. The anaesthetic properties of chloroform and ether have been made use of in medicine for a long time.

2.9.1. Procaine has been in use for over 50 years as a very satisfactory local anaesthetic. The success of procaine has led to a close scrutiny of related compounds in the hope of finding superior local anaesthetics and has resulted in the discovery of a number of drugs which allow a wide choice to be made to suit different conditions.

2.9.2. Tubocurarine isolated from curare is a valuable muscle relaxant used therapeutically as an aid to surgery. Synthetic muscle relaxants like mephenesin are used orally for the treatment of anxiety neurosis and relieving spastic conditions.

2.9.3. Among the list of drugs used for the relief of pain several additions have been made during recent years. To morphine and its derivatives have been added newer analgesics like pethidine and amidone. In the search for new analgesic drugs, the general aim has been to find substances as effective as morphine but without its disadvantages, such as respiratory depression, liability to produce nausea and vomiting, its constipating action and most important, its liability to produce addiction. Some advances have been made in this direction which have also resulted in a wide choice of drugs. The toxic effects of analgesics vary considerably among individuals and the wide choice now available makes it possible to select a satisfactory one to suit each case.

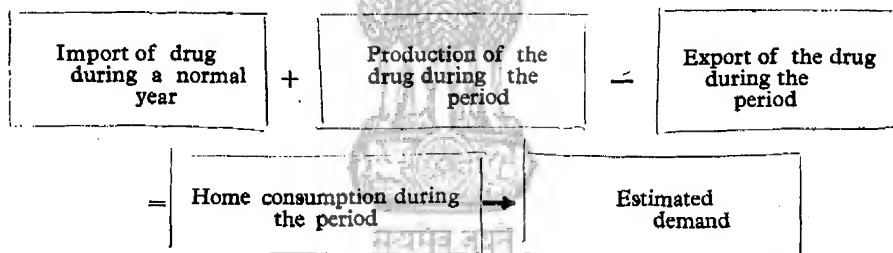
2.10. *Drugs of vegetable origin*.—Modern methods of analysis and synthesis have resulted in a greatly extended range of drugs in this category. The most important advance is due to modern pharmaco-

logical, clinical and statistical methods which have helped to separate the useful from the useless. Advances are being made in the correlation of therapeutic effect and physicochemical structure. Investigations on drugs not so far used in modern medicine but which have been long known and used traditionally in certain countries have also led to valuable additions in this group of drugs.

2.11. There is an overwhelming feeling among the members of the medical profession, public health authorities and medical educationists that a large number of superfluous and unessential preparations of foreign origin are being flooded into the Indian market. We recommend that a more comprehensive list of essential drugs should be drawn up by an expert body comprising of the representatives of the medical profession, manufacturers and the Government, and revised from time to time for inclusion or otherwise of different items to be able to keep a check on the import of unessential drugs and help in the manufacture of essential drugs.

### 3. Estimates of demand and steps necessary to meet them by increase in production:

3.1. No reliable estimates are available of the existing demand of the country for any of the drugs given in the list of essential drugs (Appendix No. 10). We have, therefore, estimated the demand roughly for some of them by the method which is represented diagrammatically below:—



Even for making this approximate estimate, we have experienced considerable difficulty in obtaining figures of imports and exports for each of the items. The Sea Borne Trade Accounts published by the Government give only the quantity and value of the imports under broad headings, which give no idea of the actual type and quantities of even the important drugs brought into the country. To enable a proper assessment to be made, the Committee strongly recommend that in future a detailed tariff classification indicating the imports of all essential drugs should be included in Import Schedules published by the Government of India. Similar information regarding exports of various drugs and pharmaceuticals should also be included in the customs schedules. These will be helpful both to the Industry and the Government to know the extent to which the country is dependent on imports and to plan the development of the Industry. At present, information concerning import of basic chemicals and intermediates required by the pharmaceutical industry is also not available. To help in assessing the demand of important basic chemicals and intermediates required by the industry, they should also be similarly classified in detail in the above schedules and their individual imports indicated.

3.2. In the absence of all these vital statistics, the Committee had to prepare a list of importers of drugs in the country, who imported essential drugs to the value of Rs. one lakh and above, and send out a detailed questionnaire to them to collect information concerning their imports. The figures of exports to India of these drugs from important exporting countries such as U.K., U.S.A., Switzerland etc., were also collected for comparison with these figures. The import figures compiled from copies of invoices maintained by the Assistant Drugs Controllers at the ports for some of the items were also made available to us by the Drugs Controller (India).

3.2.1. The following table shows the import of essential drugs compiled from the above mentioned data along with their production and installed capacity wherever they exist in the country. The estimates of demand also indicated in this table have been arrived at on the basis explained earlier.



सत्यमेव जयते



I	2	3	4	5	6	7	8	9	10	11
<b>SULPHA DRUGS (Contd.)</b>										
Sulphathiazole										
Phthalyl Sulphathiazole (Thalazole).	lbs.							1,80,000		
Succinyl Sulphathiazole (Sulpha suxidine).										
Sulphadiazine	lbs.							1,50,000		
Sulphaguanidine	lbs.							50,000		
Sulfamethyl diazine (Sulphamerazine B.P.C.)										
Sulphadimidina B.P. (Sulphamezathine)								2,60,000		
Sulpha furazole (Gangtrisin)	lbs.									
Sulphacetamide (Albucid).										
Phthalyl Sulphacetamide										
<b>3. ANTIMALARIALS :</b>										
All varieties	lbs.	95,000	47,02,103	68,186 (Quinine & Salts) 26,816 (Cinchona Febrifuge)	..	..	1,90,002	1,00,000 (Quinine & its salts) 1,00,000 (Synthetics)	..	..
Quinine and its salts	lbs.	62,241	19,25,286	68,186	..	..	1,30,427	1,00,000	2,00,000	..
Proguanil Hydrochloride	lbs.	N.A.	13,59,787	Nil.	..	..	..	..	..	..
B. P. (Paludrine).					..	..	..	..	560	..
Chloroquin and its Salts	lbs.	N.A.	N.A.	Nil.	..	..	..	..	..	..



सत्यमेव जयते







I	2	3	4	5	6	7	8	9	10	11
13. ANTI-TUBERCULOSIS.										
P.A.S. and Salts . . lbs.		93,484	11,56,428	22,028	..	..	1,15,512	1,05,000	62,700 *13,440	Processing capacity 41,300 lbs.
Isonicotinic acid hydrazide lbs. (Isoniazid).		3,107	2,48,385	2,418	..	..	5,527	20,900	(*)Anticipated) 9,000 lbs. 95,000 lbs. (Anticipated).	
14. VACCINES, SERA AND CCS ANTI-TOXINS.		N.A.	8,68,241	10,03,14,840	..	..	10,03,14,840	11,00,00,000	18,50,51,400	
15. DRUGS OF VEGETABLE ORIGIN.										
Digitalis leaf and alkaloids (Digoxin, etc.)	..	..	..	..	..	..	..	Demand is not assessable.	..	..
Ephedrine . . . lbs.		361	66,300	2,634	N.A.	N.A.	2,995	1,000	3,000	
Caffein and salts . . lbs.		8,433	1,49,529	6,218	..	..	14,651	20,000	19,000	
Strychnine . . . lbs.		Nil	Nil	18,000	..	..	..	Little demand at home.	18,000	
Emetine hydrochloride . lbs.		204	7,45,274	N.A.	..	..	..	275	160	
16. OTHER DRUGS.										
Bismuth Salts . . lbs.		55,200	10,16,000	Production recently started by M/s Chemo Pharma Ltd. Bombay.	Nil	Nil	55,200	60,000	Production recently started.	
Calcium lactate . . } lbs.		6,900	6,900	68,683	..	..	75,583	1,34,400	4,07,200	
Sodium lactate . . }		..	..	..	..	..	..	Demand not assessable	40,320	
Calcium gluconate . .		..	..	..	..	..	..	60,000 (anticipated)		



3.2.2. We, however, wish to emphasise that the estimates of demand given in these statements are very approximate and should be taken to indicate only the trends of consumption based on the present meagre data available. These estimates should be revised when more authentic figures of imports and exports become available. Wherever a wide gap between the estimates of demand and existing capacity exists, additional units should be encouraged to be put up to bridge the same. The Development Council, when formed, should review each item and suggest steps necessary for the purpose. The Committee's attention has been often drawn in this connection to the targets of production of various drugs indicated in the report of the Panel on Fine Chemicals, Drugs and Pharmaceuticals published in 1945. We are not aware of the basis on which these figures have been arrived at. In most cases they do not tally with our estimates and appear to be either out of date or too ambitious.

3.2.3. In the case of products for which certain specified capacities for production have been claimed, and their actual production has been lagging behind, the units concerned should be asked to work and produce upto full capacity at least for a certain specified period to establish evidence of their ability to work at the capacities claimed. Once this evidence becomes available, adequate assistance should be given to the industry to operate to its full capacity by enabling its products to be sold in preference to those imported.

3.2.4. The import duty on industrial machinery and scientific equipment, not made in the country, and yet required by the pharmaceutical industry for manufacturing and testing purposes, should be brought to the same level as that levied on capital equipment for other industries.

3.2.5. Assistance should be given in the form of reduction, remission or rebate of import duties on raw materials and intermediates required by the Industry. The rebate or reduction should be so adjusted as to amount to a total incidence which would be less than the duty levied on the finished products.

3.2.6. Imports of vitamin preparations under the Open General Licence (O.G.L.) should be stopped, and put on a separate quota basis, which should be gradually reduced as the indigenous production increases. Only the import of vitamins in bulk should be allowed on the O.G.L. till such time as their manufacture develops in the country.

3.2.7. The recommendations of the Development Council for pharmaceuticals and drugs, when formed, should be taken into consideration in the formulation of the import policy in so far as it affects the development of the pharmaceutical industry.

3.2.8. Drugs, whose indigenous production is deemed to be adequate, should not be allowed to be imported except to the extent of token imports considered necessary to act as an incentive for maintenance of standards and further development of the products.

3.2.9. Consistent with meeting local demands, foreign markets should be expanded for pharmaceutical preparations by permitting their liberal exports and including them while negotiating trade agreements.

3.2.10. The imports of unessential patent and proprietary medicines should be restricted. The Committee have been given to understand that the present practice of levying a heavy import duty on patent and proprietary medicines is having a salutary effect on reduction of their imports. It is suggested that this practice may be continued and the duty further increased as and when necessary.

#### 4. Cost of Production and the efficiency of the Process employed.

4.1. One of the terms of reference to the Committee refer to the cost of production and efficiency of process employed. To examine the aspect, specific questions relating to them had been included in the questionnaire issued to the Industry. The Committee regret to state that despite assurances given that all information supplied to the Committee in this regard would be kept strictly confidential, very few firms have furnished the necessary data. Even in the case of those firms, which have furnished some material, the data vary widely with respect to the same product, and the break-up of cost has not been indicated. Such information has, therefore, not been useful to come to any conclusions in regard to the cost of production and relative efficiency of the methods employed for pharmaceuticals and drugs made in the country. With the exception of a few firms, which may have some organised data, many of the manufacturers do not seem to maintain separate figures of cost for the production and marketing of their products. Since proper data would be useful even to the firms for assessing their own efficiency and determining their selling prices on a reasonable basis whenever competition makes it necessary for them to do so, we recommend that steps should be taken to ensure that all the manufacturers maintain proper records of cost data relating to their products.

4.2. As mentioned before, the activities of the pharmaceutical Industry come under two groups (i) manufacture of basic drugs; and (ii) formulation of preparations. The cost of production of basic drugs would require to be determined on the basis of conditions obtaining in each factory, while the cost of formulations would have to be determined on the basis of data collected from a number of different firms, with reference to the operations involved. Such detailed studies of cost could not be undertaken by the Committee within the limited time at its disposal and without setting up a separate Cost Accounting Wing. The Committee, however, realise the importance of this study and recommend that detailed examination of books of different firms for estimating not only the cost of individual drugs but also the cost of processing different formulations should be undertaken. Such information would then enable the assessment of relative efficiency of different firms to be made and also enable Government to take appropriate steps for fixing reasonable prices of products periodically. A separate Cost Accounting

Wing should be attached to the Development Council, when formed, for undertaking this work.

4.3. To enable the manufacturers to assess the cost of production of pharmaceuticals and drugs from imported basic chemicals and the economics of their production, the rates of customs duty levied on the various raw materials and finished products should be indicated in the Customs Tariffs separately for each item.



सत्यमेव जयते

## CHAPTER V

### STANDARDISATION, CONTROL OF QUALITY AND ADMINISTRATION

#### (a) PRESENT METHODS ADOPTED IN ADVANCED COUNTRIES

##### 1. General.

1.1. A study of the methods of standardisation and control of quality of drugs in advanced countries necessitates a brief consideration of "drug standard" in addition to a review of the machinery for enforcing legislation pertaining to drug standardisation and quality control. In this report, three countries have been selected for detailed consideration, viz., the United Kingdom, the United States of America, and Canada, as these would suffice to give a thorough insight into the trends of modern drug legislation and the machinery for its enforcement.

##### 2. United Kingdom.

2.1. The basic legislation pertaining to drugs in the U.K. had its origin in the Sale of Food and Drugs Act of 1875. The purpose of the 1875 Act was the one of making better provisions for "the sale of food and drugs in a pure and genuine condition." Three major offences against the consumer were enumerated:

- (i) It was forbidden to mix, colour, stain or powder any food or drug with any ingredient which made that food or drug injurious to health or any drug with any ingredient so as to affect injuriously its quality or potency.
- (ii) It was made an offence to sell, to the prejudice of a purchaser, any food or drug, not of the nature, substance and quality demanded. This section was by far the most important one in this enactment, and it was and still continues to be, the keystone of the enforcement sections.
- (iii) It was an offence to use a misleading label or one which falsely described the food or drug.

2.2. In 1928, the Food and Drug Adulteration Act of 1928 was enacted. This Act was a comprehensive statute and brought together the spirit of all the various food and drug enactments since and including the Act of 1875. It did not contain any substantially new concepts of law relating to food and drugs. In 1938, the Food and Drugs Act of 1938 replaced the 1928 Act. This enactment was much more than a consolidating enactment, for it recognised for the first time, the necessity of authority to establish standards for foods and to deal with advertisements and labels. It took note of the potential force of labels and advertisements as a means of informing and influencing the consumer. The 1938 Act provided, that the label should

state explicitly the substance added or the constituent abstracted, and must be of adequate size, with the required information distinctly and legibly printed and conspicuously visible. The Act further prohibited the use of a label, falsely describing any food or drug, or otherwise calculated to mislead as to its nature, substance or quality. Likewise, it also prohibited the publication of an advertisement falsely describing any food or drug or otherwise calculated to mislead as to its nature, substance or quality. In addition to the substantial advance in the field of "misbranding" through more adequate control of labels and advertisements, the legislation contained provision for the first time to authorise the Minister of Health to make regulations prohibiting or restricting the addition of any substance to, and regulating generally the composition of food. This constituted the most revolutionary change in the law.

2.3. The actual execution and enforcement of the Act is the duty and responsibility not of a Central Government department, but of certain local authorities, known as "Food and Drug Authorities". For this purpose, the United Kingdom is divided into groups on a population basis, and these groups, be they County Councils, City Councils, or Borough Councils, act as Food and Drug Authorities for their areas. Each Food and Drugs Authority must appoint a Public Analyst, whose appointment requires the approval of the Minister of Food. There are over 200 Food and Drugs authorities and about 120 public analysts. Every public analyst is an independent expert, and is, therefore, in a position to report to his authority on any sample without regard to the views, which might be held by other public analysts. Sampling of food and drugs is carried out by sampling officers appointed by the Food and Drugs authorities.

2.4. One aspect, which is perhaps worthy of observation relates to the relative importance given in the Food and Drugs Act to *treatment of drugs*. The present Act and the preceding Acts purported to be drug Acts as well as food Acts. The original Act of 1875 dealt with the subject of Food and drugs in term of same equality, but the subsequent legislation practically ignored the subject of drugs and the present Act of 1938 is essentially a public health and food statute and is not in any sense a drug statute. Out of 103 Sections of the Act, a bare half a dozen include the word, "Drugs". Thus, in considering drug legislation in United Kingdom, it becomes essential to consider other enactments such as the Therapeutic Substances Act, the Medicines and Pharmacy Act, to mention only two. Further, it is a curious situation, that none of the English Statutes which deal with "Drugs" purport to establish an official standard for drugs, nor does the 1938 Act give the Minister of Health, power to establish standards for drugs, as it does in the case of foods. The British Pharmacopœia, which is a statutory publication, is only a presumptive standard in the United Kingdom.

2.5. The only drugs for which statutory standards exist are those covered by the Therapeutic Substances Act, 1925. In spite of the all-embracing title of this Act, the number of substances controlled is small. As has been explained above, quality control in the U.K. depends on the activities of public analyst and few, if any, of these



officials have the facilities or experience to carry out biological assays. The Act was, therefore, passed to create a means of controlling substances, of which the purity or potency cannot be adequately tested, by chemical means. It exercises a much closer type of control than the Food and Drugs Act. When the Act was first passed, the substances covered were vaccines, sera, toxins, anti-toxins and antigens, arsphenamine and "analogous substances used for the specific treatment of infective disease", insulin and injectable post-pituitary extract. Provision exists in the Act for bringing additional substances under its control by the issue of departmental regulations without prior reference to Parliament, and in addition to those listed above, the other "therapeutic substances" now are: Surgical ligatures and sutures; preparations of human blood; organic substances having the specific biological action of curare, and preparations the purity or potency of which cannot be adequately tested by chemical means; penicillin and its injectible preparations; Aureomycin and Streptomycin. The Act prohibits the manufacture for sale of any therapeutic substance, unless a licence is first obtained from the proper authority. The conditions, which must be complied with before a licence is issued, are set out in regulation. The licence, which has to be renewed every two years, is issued, only after the Ministry of Health is satisfied, on a report of an inspector, that the licensee's technical staff, premises and plant are adequate for manufacturing and testing purposes. The licensee must allow his premises to be inspected at any time; he must, if so required, supply samples of each batch to the Ministry and undertake not to issue any for sale until authorized to do so. Records must be kept of tests applied to each batch and copies must be supplied to the Ministry, when required. For each therapeutic substance, a non-proprietary name is specified, which must be printed on labels in letters not less conspicuous than those in which any proprietary name is printed. This non-proprietary name is termed in the Act a 'proper name', a somewhat curious designation which seems to imply that a trade-mark name is improper. In practice, the requirements is a satisfactory compromise between the interests of manufacturers, who can still advertise their brands of therapeutic substances, and the official views of organized medicines that brand names confuse the doctor and lead to irrational therapeutics. Labels must show the number of the licence under which the substance is made, the manufacturer's name and address, the potency, the expiry date, storage instructions, and certain other details of minor importance. The object, of course, is to ensure, that any particular container can be readily traced back to the manufacturers' records and the tests carried out on it checked up. Details for carrying out tests for sterility and for freedom from abnormal toxicity are specified in the general part of the regulations, while specific requirements applicable to the individual substances, including tests for purity and potency, are described in a schedule to the regulations. The Act also prohibits the import of therapeutic substances into the U.K. except under a licence and provided that the strength, quality and purity conform to the requirements of the regulations. A licence can be obtained to import for purposes of research a therapeutic substance, which does not so conform, and similar provision is made to enable a manufacturer to make solely for export a therapeutic substance not conforming to the official requirements, but in granting the licence regard must be "had to the nature of any

arrangements for regulating the manufacture and sale of the substance in operation in the country to which the substance is to be exported." The Inspectors appointed under the Act visit the different Laboratories to see that the manufacture is properly carried out. They buy samples for analysis and tests by a central laboratory—the National Institute for Medical Research.

2.6. Offences against the Act are punishable on the first occasion by a fine and on subsequent occasions by a fine or imprisonment, but so far as is known, prosecutions have never been brought. The power to revoke a licence is perhaps a more effective weapon; but in any event the manufacture of the substances concerned is in the hands of firms of repute, which are always ready to cooperate with the Ministry of Health in any reasonable way to achieve the objects of the Act and Regulations. In framing the various regulations, consultation with an advisory committee is required by the Act, the committee consisting of representatives of the Ministry of Health and the corresponding departments in Scotland and Northern Ireland, of the Medical Research Council, the General Medical Council, the British Medical Association, the Pharmaceutical Society and the Institute of Chemistry. It will be noted that the committee does not include any representative of the manufacturers. It is understood that, in practice, members of the committee are usually consulted by correspondence and the committee as such rarely or never meets.

2.7. Another important piece of drug legislation in the U.K. to which reference must be made is the Pharmacy and Medicines Act of 1941. It is the responsibility of the pharmaceutical Society to enforce this Act, which has the following three main purposes:—

- (i) It makes it an offence for any one to take part in the publication of an advertisement for any article in terms calculated to lead to its use for the treatment of human beings for any of the following diseases: Bright's disease, cataract, diabetes, epilepsy or fits, glaucoma, locomotor ataxia, paralysis, tuberculosis.
- (ii) It requires the disclosure on the label of details of the composition of "any article consisting of or comprising a substance recommended as a medicine," when the article is sold by retail.
- (iii) It restricts the retail distribution of any such article as mentioned in the preceding paragraph to medical practitioners, dentists, "authorized sellers of poisons" (i.e., retail pharmacies—see below) and, subject to conditions, persons who have served a regular apprenticeship to a pharmacist or to a body corporate, which is an authorised seller of poisons.

2.8. The control on antibiotics in the U.K. is rather stringent. The quality of penicillin and streptomycin is controlled through regulations issued under the Therapeutic Substances Act. Distribution of the two antibiotics is controlled under another misleadingly named Act, the Penicillin Act, 1947. Although originally relating

only to penicillin, the Act contains a clause by which "such other antimicrobial organic substances produced by living organisms, as may be prescribed by regulations" may be brought within its control. Up to the present time, the additional antibiotics, to which the Act has been applied, are streptomycin, chloramphenicol and aureomycin, these being the only antibiotics available commercially in the U.K. at the present time. Provision is made for the inclusion of synthetic antibiotics having chemical properties identical with those of substances coming within the above description. The Act applies to the antibiotics themselves and to preparations containing any proportion of any of the antibiotics as an ingredient. Substances controlled under the Act can be supplied only by doctors, dentists, veterinary surgeons or persons acting in accordance with the directions of one of these (for example, nurses) or by pharmacists and authorised sellers of poisons acting on a prescription signed and dated by one of them. Wholesale transactions and sales to doctors, hospitals, etc., are exempted from the restrictions. A prescription may be dispensed only once, unless it expressly directs, that it may be dispensed at specified intervals or a specified number of times; a mere general instruction on the prescription such as "may be repeated" must not be acted upon.

2.9. The law relating to sale of poisons, in general, and of narcotic drugs, in particular, involves a vast amount of detail. The administration and enforcement of the legislation relating to poisons is a responsibility of the Pharmaceutical Society, which operates in this respect through a number of inspectors. The routine enforcement of the narcotic drugs legislation is to some extent undertaken by local police officers, but in special cases, assistance of more experienced officers of the government department concerned is taken. The statutory law relating to poisons is the Pharmacy and Poisons Act which contains detailed provisions relating to manufacture, storage and sale of what are termed "listed poisons". The Act provides for the creation of a Poisons Board consisting of representatives of the Pharmaceutical Society, various government departments, various medical bodies and the Royal Institute of Chemistry. Its functions are to make recommendations to the Home Secretary regarding substances to be included in the "Poisons List" and the Rules to be applied to them. The legal requirements affecting the sale of poisons are contained in the Poisons Rules 1949, as amended. These prescribe among other things, details as to labelling of poisons. The legislation pertaining to narcotic drugs is the so-called Dangerous Drugs Acts, 1920 to 1932, and a relatively extensive series of regulations issued thereunder. The Acts deal with possession, sale, manufacture, import, etc., of opium prepared for smoking, crude drugs such as coca leaves, Indian hemp and raw opium and medicinal dangerous drugs, which have dangerous habit forming properties.

2.10. Thus it will be seen, that U.K. Drug Law is a mosaic of legislation, partly statutory but mainly delegated, enacted over a period of years, each piece of legislation dealing with a relatively specialised but restricted field, sometimes without much regard to the provisions of other Acts and Regulations. It is worthy of note, that there is no legislative control on imported drugs except those covered by the Therapeutic Substances Act, nor is there any piece

of legislation dealing with exports. Cosmetics are also not dealt with in any of the drug statutes. Lastly, there is no control, whatsoever, over the introduction of new drugs.

### 3. The United States of America.

3.1. The Food and Drug Administration until recently was a separate Bureau in the Federal Security Agency, but now it functions under the Department of Health, Education and Welfare. It is a separate government organisation employing scientific staff, inspectors, etc. The principal responsibility of the Administration is the enforcement of the Federal Food, Drug and Cosmetic Act. The headquarters organisation decides as to whether or not seizures, prosecutions and injunctions recommended by the field staff should be carried out. Its duties also include a wide variety of general supervisory administrative tasks, including such matters as budget, finance, personnel and new legislation. One of the most important functions is an advisory service through consultation and correspondence with manufacturers, who wish to get information about the application of the law to their products.

3.2. The Department is divided into the following thirteen divisions:—

(i) *The Division of Field Operations.*—This is directly responsible for supervision of the field force. It maintains the day-to-day contacts with the field organization and ensures that the acts are enforced uniformly throughout the United States. It prepares and conducts training programmes for the field force. It includes a total of eight professional people, all of whom have had extensive experience in the field either as chemists or inspectors. Quite naturally, the nature of their duties requires them to visit the various field offices at frequent intervals.

(ii) *The Division of Program Research.*—This is responsible for preparing programmes of operations covering each type and kind of commodity subject to regulation. It assembles statistical and other information concerning the various food, drug, and cosmetic industries, and considers the likelihood and evaluates the seriousness of violations. Based on this information, and after a study of the size of the industry in each of the field districts, it determines the approximate number of man-hours to be spent in investigations in each of these industries. Its planning is the keystone upon which are built plans designed to guarantee that all segments of a nationwide industry will receive the same proportionate amount of regulatory attention.

(iii) *The Division of Regulatory Management.*—This is also staffed with technically trained people. Its task is to collect and assemble the factual evidence acquired in preparation for trial of contested cases. It directs the development of evidence cases designed to lead to precedent-establishing court contests to interpret the law. In the enforcement of the Food, Drug, and Cosmetic Act, complex scientific evidence is almost invariably required. Since the statute covers with a wide variety of different commodities, the factual evidence necessary for presentation in court covers the sciences of chemistry, pharmacology, bacteriology, medicine, veterinary medicine, microscopy,

nutrition, and others. It is imperative that when the factual side of a lawsuit is presented, it be carefully expressed so as to be easily understood by attorneys, by juries, and judges. This office, of course, maintains a close relationship with the General Counsel's Office, and through it with the various United States attorneys throughout the country.

(iv) *The Division of State Co-operation.*—This has as its primary responsibility a close co-operation with state and local food and drug enforcement officials. They meet these officials frequently to prevent unnecessary duplication and bring about, as nearly as possible, uniformity of enforcement by the national and local food and drug officials. This office also has responsibility for making recommendations as to what foods should be standardized. In discharging this obligation, it works closely with local food and drug officials and with the field staff of the Food and Drug Administration.

(v) *The Division of Business Operations.*—This is concerned broadly with all phases of housekeeping. It prepares budgets, maintains fiscal records, and discharges various responsibilities concerning personnel. It also furnishes information to the public relating to the Food and Drug Administration.

3.2.1 The following eight technical divisions are responsible for advising the Food and Drug Administration as to the scientific facts within their provinces. Each of them determines the Administration's policy within its respective field. Laboratories are maintained, where research is conducted, which is designed to develop new or improved methods of analysis of foods, drugs or cosmetics. It is their responsibility to keep abreast of technical changes in the industries and to keep informed about scientific advances within their respective fields. In addition to the research, which they conduct, a number of them undertake examinations of individual samples, where the nature of the tests to be made is such that they cannot be carried out in the field laboratories.

(vi) *The Division of Medicine.*—This determines the medical policy of the Food and Drug Administration in such fields as the therapeutic value of drugs and devices. It determines the safety of these commodities and discharges a wide variety of responsibilities to implement the enforcement of the Act with respect to drugs and therapeutic devices.

(vii) *The Division of Food.*—This devises physical and chemical methods to determine the identity and quality and to detect adulteration of foods. It plays a large part in formulating the evidence to be presented by the government at food standards hearings.

(viii) *The Division of Microbiology.*—This is staffed with bacteriologists and microscopists. They develop the bacteriological and micro-analytical methods for detecting filth and decomposition in foods and drugs. They have a large project dealing with food poisoning. They are leaders in many phases of sanitation control. One of their routine tasks is to test hundreds of samples of drugs intended for injection and of sutures used to close wounds after operations and to determine whether these are free from living bacteria.

(ix) *The Division of Antibiotics*.—Its principal responsibility is the certification of penicillin, streptomycin, aureomycin, chloramphenicol, and bacitracin. It conducts researches on new antibiotics and discharges a number of related responsibilities.

(x) *The Division of Cosmetics*.—This is responsible for the development of methods for the examination of cosmetics generally, and, in addition, maintains a laboratory where all coal-tar colours used in foods, drugs, or cosmetics are certified, before they can be legally employed.

(xi) *The Division of Pharmacology*.—This maintains one of the largest laboratories of this type in the world. Its duties involve the assay of certain drugs and glandular products by tests on animals. It determines the toxicity of ingredients of foods, drugs, and cosmetics. Each batch of insulin has to be certified by it before it can legally be sold.

(xii) *The Division of Nutrition*.—This develops methods of assay of vitamins and other ingredients pertaining to the nutritive quality of foods and drugs. As a routine, it conducts tests for vitamins and other nutritional factors by animal experiments.

(xiii) *The Division of Pharmaceutical Chemistry*.—This division has been formed recently. It was formerly a section of the Division of Medicine. The growing importance of the work, for which it is responsible caused it to be made into a separate division. The principal tasks assigned include the development of chemical and physical methods for testing drugs, and the routine analysis of many samples, which the field staff are not equipped to conduct. It tests, for example, the accuracy of clinical thermometers and the strength of surgical sutures. It serves as the Administration's adviser in the broad field of pharmaceutical chemistry.

3.3 For the purposes of enforcement of the laws charged to the Food and Drug Administration, the country is divided into sixteen field districts. Each of these district offices maintains a laboratory and an inspection staff. In addition to the district laboratories themselves, three other small laboratories were established in cities within the district territory. In 39 other cities one or more resident inspectors are assigned; they work under the direction of the district offices. Thus the Food and Drug Administration has offices in 58 cities scattered throughout the United States. Most of the approximately 60,000 samples of foods, drugs, cosmetics, and caustic poisons collected annually are examined in the 19 field laboratories.

3.4 *Food and Drugs Legislation*.—The laws pertaining to Foods and Drugs are both State and National in scope. Most of the States have their own separate laws. In several states, the laws follow the general principles of the Federal Act, but in some, there are material deviations. At present, the control of drugs is exercised by the Federal Food, Drugs and Cosmetic Act. It is designed to prevent the manufacture, sale or transportation of adulterated or misbranded or poisonous or deleterious drugs and medicines, among others, and for regulating traffic therein. The provisions of the Act apply to adulterated or misbranded drugs, which have been shipped or delivered for shipment in inter-State commerce, or which are exported or offered for export to foreign countries, or which are being transported

in inter-State commerce for sale or have been transported in inter-State commerce, or which have been received from a foreign country, or which are manufactured, sold or offered for sale in the district of Columbia, territories of the United States or insular possessions. Each State has complete control over inter-State commerce and drugs produced within its limits.

3.5. The manufacture of adulterated or misbranded drugs in any territory or district of Columbia, the shipment of any adulterated or misbranded drug, out of or into, or the delivery of any such article in original unbroken packages in, any State, territory or district of Columbia or its sale in or export from the district of Columbia or the territories of the United States, is made punishable by the Act. Adulterated or misbranded articles in the course of transmission may be seized for confiscation by a process of libel for condemnation, and may be destroyed or sold or delivered to the owner, on his executing a bond to the effect, that they will not be disposed of contrary to the provisions of the Act.

3.6. The Act recognises the standards in the United States Pharmacopœia and the National Formulary as officially governing drugs or National Formulary. Drug is regarded as adulterated, if it differs from the accepted standard of strength, quality or purity and any other drug, if it falls below the professed standard of quality; but, in the former case, it will not be treated as adulterated, if the actual standard of strength, quality or purity be plainly stated on the container. Drugs recognized in the United States Pharmacopœia or National Formulary should be analysed by the tests laid down therein and other drugs should be analysed by methods prescribed by the Association of Official Agricultural Chemists or by methods satisfactory to the Food, Drug and Cosmetic Administration. 'Misbranding' takes place if the label of a drug contains a statement, design or device regarding the drug, or its ingredients, or of their curative or therapeutic effect which is false or misleading. Imitation of, or sale under the name of, another article, or the substitution of the contents of a package with other material, or the failure to bear on the label a statement of the quantity, or proportion of specified ingredients such as alcohol, etc., would also amount to misbranding.

3.7. No special supervising control is exercised over patent or proprietary medicines except as regards misbranding. It is expressly mentioned in the regulations that statement of the formula is not required on the label except in so far as it may be necessary to secure freedom from adulteration or misbranding.

3.8. The Act embodies special procedure for dealing with imports. The enforcement of the provisions relating to imported drugs is under the local direction of the officers of the stations of Food and Drug Administration. Collectors of Customs act as administrative officers in carrying out directions relative to the detention, exportation and destruction of merchandise and action under bond in case of non-compliance with the provisions of the Act. Merchandise will not be delivered to the consignee prior to report on examination, unless a bond for the value of the goods is given. If violation of the Act is disclosed, a formal enquiry will be held after notice to the importer. If goods are to be refused entry, the Chief of the Station will notify

the Collector of it, who will call on the importer to export or destroy them in three months. The goods may be released in certain cases after relabelling or compliance with stipulated conditions under the supervision of the Inspector. The Importer is required to pay to the Administration for the services of the Inspector, which are charged on the basis of time spent. If the goods are not "conditioned" within the period allowed, they will be exported or destroyed. The Collector will report the final action taken to the Chief of the Station.

3.9. An article of drug intended for export is not adulterated or misbranded within the meaning of the Act, if it is established by the shipper or exporter that the article is prepared, or packed according to the specifications, or directions of the foreign purchaser, and that no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which the article is intended to be shipped. Such an article should be labelled so as to show that it is intended for export and is prepared, or packed in accordance with the specifications or directions of the foreign purchaser. If, however, it is sold or offered for sale for domestic consumption, it will be subject to the provisions of the Act regarding domestic sale. The Regulations permit the import of adulterated foods or drugs for technical or restricted use under certain conditions.

#### 4. Canada:

4.1. The Act in force in Canada is the Food and Drugs Act. It defines 'adulteration' and 'misbranding' of foods and drugs on the line of similar Acts in other countries. Every drug is to be deemed to be adulterated if its strength, quality or purity falls below the professed standard under which it is sold or if, when exposed or offered for sale under a name recognized in the latest edition of the British Pharmacopoeia or of any foreign pharmacopoeia or in some generally recognized standard work on materia medica or drugs, it differs from the standard in strength, quality or purity specified therein. The British Pharmacopoeia and the standards therein are specially recognized and, in the absence of any indication to the contrary, they govern every drug.

4.2. Any person, who by himself or his agent manufactures for sale, or sells any adulterated or misbranded article of food or drug, is guilty of an offence under the Act. Labelling as to 'purity' is prohibited, so also any misleading statements. The Act regulates the distribution of samples.

4.3. The Council of any city, town or other municipality may appoint inspectors. The Governor in Council has the power to make regulations, prescribing the duties of Inspectors and for designating as Government Analyst any member of the technical staff already appointed to the services of the Department of Health. The Inspectors are empowered to inspect and procure samples from manufacturers or vendors or from consignments sought to be imported into Canada and submit them for analysis by the Government Analyst. Any person can also submit samples to the Government Analyst for analysis. The Government may initiate prosecution in the case of



adulteration or misbranding. The Analyst should give a certificate as to the adulteration, and its injurious character; and it is open to the aggrieved party to contest it before the Chief Government Analyst, who may cause it to be re-analysed. The certificate of the Chief Government Analyst is final and conclusive. Proof, that the article was a bonafide purchase in the same state, as that in which it was sold, and that the vendor, with reasonable diligence, could not know of adulteration or misbranding, is a good defence. Either, he or the prosecutor, may in such a case, lay information against the third party, from whom the purchase was first made and the court can decide on the merits of the case.

4.3.1. Articles of drug, which are reported as adulterated or misbranded by the Government Analyst, may be seized and forfeited. Materials used for purposes of adulteration may also be seized, analysed and treated similarly.

4.4. The Canadian Act authorises the Governor in Council to adopt regulations prescribing standards of quality for any drug, to prescribe packaging or labelling, to prevent deception as to the character, strength, quality or quantity of any drug, to prohibit or restrict ingredients, which may be injurious to health to define the conditions of sale of any drug, and to avoid false, exaggerated, or misleading claims. The Act has appended to it two Schedules 'A' and 'B'; the first enumerates specific conditions, for which no drug may be recommended or sold to the general public, and the second provides a list of drugs, for which special regulations are deemed necessary.

4.4.1. A list of disease conditions for which no drug may be recommended or sold to the general public is published by Government (Schedule 'A') which is revised from time to time. The diseases listed in them include cancer, diabetes, tuberculosis, venereal diseases, and disorders of the menstrual flow. The purpose of this schedule is to obviate the necessity for proving that the claims are false, and more effectively, to discourage exploitation of the public through the sale of articles for diseases that cannot be treated safely and effectively through self-medication.

4.4.2 Special regulations respecting several classes of drugs described in Schedule 'B' have been provided for. This schedule is revised from time to time, by adding new classes of drugs or by deleting some of them. Schedule 'B' is divided into five parts according to the nature of the drug and the type of control deemed necessary. Part I includes hormones; Part II includes drugs that purport to be sterile and are intended for parenteral use; Part III includes drugs derived from micro-organisms like antibiotics, and biologicals and analogous preparations; Part IV includes organic compounds of arsenic, and analogous products for parenteral use; and Part V consists of 50 specified drugs. Standards of quality and potency prescribed for these drugs by the Canadian Government, take precedence over the standards laid down in the British Pharmacopoeia. If the Administrator considers tests and methods of assay prescribed in an official compendium insufficient, he may, after calling attention of the revision body to the insufficiency and allowing a reasonable time for revision, prescribe tests and methods of assay. The Schedule B drugs in Part II (sterile drugs for parenteral use) and in Part III

(antibiotics, viruses, among others) are subject to stringent licensing control of manufacturers. The licence is an annual one. It is issued after inspection of the plant, study of the qualifications of personnel, and study of the principles of manufacture and the equipment employed. It is conditioned upon the licensee's maintaining the premises under the direct control of a responsible qualified person and keeping satisfactory records of manufacture, testing, and distribution.

4.5. The manufacturer's right to keep off the label of proprietary and patent medicines, the formula or list of medical ingredients, has been conceded, at the same time control has been established to protect the public by licensing. The Proprietary or Patent Medicine Act, administered by the Minister of Health and Welfare, establishes the special controls. Proprietary or patent medicine is defined as an artificial remedy or prescription manufactured for the internal or external use of man, the name, composition or definition of which is not to be found in official pharmacopoeias, or upon which the true formula or list of medicinal ingredients is not conspicuously placed. A drug is considered a patent medicine only, if the ingredients thereof are not listed. The Canadian Act seems to give a manufacturer the choice of listing the ingredients and coming under the Canadian Food and Drugs Act or omitting such listing and being governed by the terms of the Proprietary or Patent Medicine Act. Under the Act, the manufacturer of a proprietary or patent medicine must register his formula and statement of uses with the Minister before offering the drug for sale. No claim can be made that the medicine will cure a disease. False and exaggerated claims are prohibited. The application for registration must state the type, and quantity of certain dangerous drugs contained in the medicine. Some narcotic and dangerous drugs are prohibited in patent medicines. The Minister may require that manufacture be continually supervised by a chemist or pharmacist. Upon registering, the manufacturer is given a registration number, which must appear in the labelling of the article. An annual licence to sell the medicine without disclosure of the formula is issued and it may be revoked for a sufficient cause. Presumably, revocation could be based upon the use of false or exaggerated claims. No proprietary or patent medicine can be sold from door-to-door, in public places, or high-ways, or through the mails. Failure to register the drug subjects it to seizure and the manufacturer to prosecution.

4.6. The Canadian Act authorises the Governor in Council to promulgate regulations defining the conditions of sale of any drug. Under this authority, a group of drugs has been limited to sale on the individual prescription of a physician. This is done by establishing a list of drugs that may be sold only on prescription. Articles are listed in general terms, for example, barbituric acid and any salt, homologue, or derivative thereof. The allowable claims that may be made for vitamins are established by regulations. These regulations are, incidentally, a result of cooperation between government and industry. The regulations prohibit entirely the use of testimonials on the label or in advertising. They prohibit any assurances to the general public regarding results that could be obtained from treatment by vitamin medication or from the addition of vitamins to the diet. Vitamin products sold to the general public must

contain an optimum minimum daily requirements and should not contain more than a specified maximum. Vitamin products containing more than the maximum are regarded as drugs for therapeutic use only and may not be advertised to the general public. The only general claims, which may be made to the public based upon the vitamin content of a food, dietary supplement, or drug, are the following:

- (i) that vitamins are necessary for the normal functioning of the body;
- (ii) that they aid in growth;
- (iii) that they may help to maintain appetite; and
- (iv) that they may help to maintain normal resistance of the body to infection.

The regulations also provide that certain specific claims may be made for each vitamin. They appear to be specially well-suited to the protection of the public, because of the many speculative and enthusiastic claims, that have been made by various investigators, as to the value of the vitamins in the prevention and treatment of illnesses. Some theoretical basis can be found in the scientific or pseudoscientific literature for almost any claim of curative value for almost any of the vitamins. The Canadian authorities appear to have allowed only those claims that have been justified by sound investigational work.

## (b) CONTROL OVER QUALITY OF PHARMACEUTICALS IN INDIA

### 1. Position till 1930.

1.1. India was largely dependent on foreign imports for drugs of modern medicine until after the First World War. The chief countries, from which these imports were received at that time, were Germany, France and Great Britain. As a result of the chaos, that followed the First World War, there was a mushroom growth particularly on the Continent of Europe of unethical drug manufacturers, who began to trade in faked and adulterated drugs with the East. This was particularly felt, as there was practically no Indian manufacturing industry to cater to the needs and requirements of modern medical practice. During the years from 1919—26, the Indian market became flooded with adulterated, substandard and faked drugs; and as no properly established organisation to control and check this menace existed, spurious and substandard drugs were sold openly at prices, which bore no resemblance to those of genuine products. Added to this, the medicines which were made available to the public, did not contain the required dosage. This state of affairs naturally had its repercussions on modern medical practice and the public. Protests arose from these quarters, which created a strong public opinion against the fraud, that was being perpetrated on the unwary and sick public, by sale in the open market of counterfeit drugs and adulterated and substandard medicines. Attention was also focused on it by scientific journals, press and public propaganda.

1.2. In 1927, the late Sir Henry Gidney, a member of the Legislative Assembly, drew the attention of the House to what he described as the "Quinine Fraud", in which he produced definite evidence before the Assembly to prove that quinine tablets that were sold to the public contained either no quinine at all or were mostly chalk containing traces of quinine. He asked the Government to take steps to stop the existing evil of wide-spread adulteration of drugs in the country. In the years following, this evil was again forcibly brought before the Council of State by the Hon'ble Sir Haroon Jaffer, who moved a Resolution, recommending to the Governor General in Council to take immediate measures to control the trade in drugs and medicines by legislation, with a view to regulate their standardization, manufacture and sale. He characterised the then existing state of affairs as a great menace to public health and pressed for efficient safeguards to ensure the authenticity of medicines offered to the public. The commercial community also testified to the gravity of the situation. Genuine products could not find market due to the low prices at which faked substitutes were offered for sale, which affected the pharmaceutical industry to a great extent.

## 2. Drugs Enquiry Committee:

2.1. As a result of these protests, the Government of India in the late Department of Education, Health and Lands, appointed a Drugs Enquiry Committee in 1930, under the Chairmanship of Colonel R. N. Chopra, to go into the question of adulterated and sub-standard drugs sold in the country, both imported and indigenously manufactured, and to recommend steps by which this menace could be controlled and ethical drug trade established in India. This step marked the beginning of Drug Control in this country. The Drugs Enquiry Committee carried out a thorough examination of the problem, in all its aspects, and submitted a report in 1931.

2.2. They classified the drugs manufactured or sold in the country under the following broad categories :

- (1) Indigenous crude drugs.
- (2) Drugs of indigenous manufacture :—
  - (a) Non-biologicals.
  - (b) Biologicals.
- (3) Imported drugs.
- (4) Drugs for export.
- (5) Patent and proprietary medicines.

The important general findings of that Committee in respect of quality are summarised below:—

"The Committee has considered the problem in all its aspects, and feels convinced that it is justified in coming to the conclusion that the drugs in the Indian market are not above reproach and that many of them are of impure quality and defective strength. The evidence points to the conclusion that the traffic in such drugs is extensive and indiscriminate and that the strong language used by

some of the witnesses in characterising the situation is by no means undeserved or exaggerated. It is not possible to estimate the exact extent with greater precision."

"The evidence left no room for doubt that, in regard to adulteration, deterioration or tampering with the quality or strength of drugs, very little distinction can be made between imported and locally manufactured medicinal preparations. Even some of the preparations of the Government Medical Store Depots were called into question by some of the witnesses."

2.2.1. With regard to biological products, it was reported that even imported preparations, manufactured by reliable firms, having an established reputation and employing a competent staff of biochemists and bacteriologists, were sometimes found to be not upto standard. For instance, a number of sera, imported into this country, had strength much below the titre mentioned on the label. Many vaccines were also found to have deteriorated considerably. Certain gland extracts and preparations were defective and faulty, showing considerable variation in their activity and, in some cases, were quite inert. Insulin prepared by reliable firms, was found absolutely useless. The following extract from the Report explains the causes :—

"The variations in the activity of such products imported into India may be due to several reasons. Firstly, the drug may not be up to the prescribed standard. Owing to the unprotected condition of the Indian market, the facilities and the temptations for the sale of all kinds of inferior and deteriorated products are many and irresistible. Some of the importers do not hesitate to descend to the vile practice of getting hold of time-expired biological products from the European market, and importing them into India and selling them to dealers at a very cheap rate. Secondly, the products when sent out by the manufacturers may be perfectly sound and up to the standard, but may lose their activity during transit or storage."

2.2.2. With regard to biologicals manufactured in this country, there appeared to be general satisfaction as regards quality of vaccines and sera, though, it was noted that these were produced on a very small scale. The position in regard to organo-metallic compounds of Arsenic and Antimony—many of which were very potent—was far from satisfactory. These could be manufactured by anyone and put on the market without properly testing their strength or determining their toxicity.

2.3. As regards imported drugs, considerable emphasis was laid in the report on the fact that many foreign firms, which exported drugs to India, manufactured them specially for India, and exported drugs of a quality that were condemned by the authorities for their home consumption. It was noted that, whereas foreign Governments protected their own people by special Drugs Act, the same Governments allowed firms to export drugs to India without any State control.

2.4. The position of "crude indigenous drugs" and "drugs for export" at the time of Chopra Committee report may be taken together, as the former constituted the bulk of drugs for export. There was no control, whatsoever, on the cultivation, collection, storage, sale and export of drugs with the result that their potency and therapeutic activity were always a matter of conjecture.

2.5. The following main recommendations were made by the Committee:—

- (i) Enactment of a comprehensive all-India legislation for the control of drugs and Pharmacy either as a combined Act or a separate Drugs Act and a Pharmacy Act.
- (ii) The setting up of an adequate machinery for control, inspection and testing of drugs to ensure uniformity of proper standards of purity and strength. Among other things the Committee suggested that a well-equipped Central Drugs Laboratory with competent staff (Experts of various branches of drug standardization) should be set up at the Centre and similar laboratories should be set up in the Provinces to work in close liaison with the Central Drugs Laboratory; and
- (iii) The setting up of a Central Pharmacy Council and State Pharmacy Councils with Registration Tribunals etc., for controlling, training, registration, etc., of pharmacists.

### 3. Drugs Act, 1940:

3.1. For a variety of reasons, the Government of India could not give effect to the scheme outlined by the Chopra Committee until January, 1937 when the Biochemical Standardization Laboratory was established in Calcutta, as a first step towards a more elaborate organisation for testing of drugs. This laboratory was set up to serve as a nucleus for the future Central Drugs Laboratory envisaged in the Chopra Committee Report. About the same time, legislation for the control of Drugs was in a drafting stage. In the meanwhile changes in the legal and administrative policy of the Central Government took place, as a result of the enactment of the Government of India Act of 1935, the subject "drugs" became a Provincial responsibility, the Centre being responsible only for imports. As a result a "Drug Import Bill" was prepared and placed for consideration before the Assembly in 1939. This, however, did not find favour with the public and all the Provinces clamoured for a uniform and comprehensive Legislation. This led to the introduction in 1940, of the Indian Drugs Bill in the Central Legislature. It was passed and received the assent of the Governor General in Council the same year and became the Drugs Act, in 1940. By this time the Second World War was in full swing, and India's commitment to War, both in personnel and resources, became more and more pronounced. It was not possible during this critical phase to implement this legislation of a longterm character in the country, and the implementation of the Act was delayed.

### 3.2. The main features of the Drugs Act, 1940 are:—

#### *Functions of the Central Government:*

- (i) Constitution of a Statutory Board, called "The Drugs Technical Advisory Board" to advise the Central and the Provincial Governments (now State Governments) in technical matters relating to the Act.
- (ii) Establishment of Central Drugs Laboratory.
- (iii) Constitution of a Drugs Consultative Committee consisting of two representatives of the Central Government and one each of the State Governments, to advise all the Provincial Governments (now State Governments) in matters tending to bring about uniformity in the administration of the Act.
- (iv) To control standards of imported drugs and to make rules in consultation with the Board for regulating the import.
- (v) Establishment of adequate machinery for administration.

#### *Functions of the State Governments:*

- (i) To control manufacture, sale, and distribution of drugs by the establishment of an adequate machinery consisting of licensing authorities, Inspectors and Government Analysts.
- (ii) Establishment of State Drug Control Laboratories.
- (iii) To make rules in consultation with the Drugs Technical Advisory Board for giving effect to the above.

3.3. The Central Government established the Drugs Technical Advisory Board in 1942 and drafted Rules to give effect to the Drugs Act, 1940 covering all aspects of the Legislation. These Rules were published for comments from the public as well as those interested in the manufacture, sale, distribution and import of drugs into India and also the Provincial (now State) Governments. All the comments received were examined by the Drugs Technical Advisory Board in 1945, and the final Drugs Rules as recommended by the Board were adopted by the Central Government in the year 1945 as "Drugs Rules, 1945". In order to secure uniformity, the Central Government Drugs Rules were adopted by the Provincial Governments as far as they were concerned.

3.3.1. The Biochemical Standardization Laboratory, established in 1937, was developed and eventually converted into the Central Drugs Laboratory in 1947 for carrying out the following main functions:—

- (i) To test samples of imported drugs sent to it from ports;
- (ii) To grant certificates of registration in respect of patent or proprietary medicines, which do not have their composition disclosed on the label. A Patent or proprietary

medicine is one, which is a prescription or a remedy and not included in the official Pharmacopoeias or which is not recognised by the permanent Commission on Biological Standardization of the World Health Organisation;

- (iii) To test samples of drugs referred to it by courts of Law in disputed cases. The report of this laboratory is taken to be final and as such, this laboratory functions as an appellate body in respect of drug standards; and
- (iv) Any other function assigned to it by the Government.

The function of the Central Drugs Laboratory in respect of certain drugs such as sera, vaccine, toxins etc. has been assigned to the Central Research Institute, Kasauli.

3.4. In order to implement the Legislation uniformly Conferences of Provincial Representatives were convened twice in the year 1945-46 by the then Health Department, Government of India, where preliminary problems concerning the implementation of the Legislation were discussed. A Drugs Consultative Committee was established in 1948.

3.5. In order to regulate imports the Central Government established organisations at the Centre and at the ports of Bombay, Madras and Calcutta during 1946-48 and very recently one in Cochin, the above sea-ports having been notified by the Central Government as points of entry for the import of drugs. Drugs can only be imported at these points by sea and certain other specified air ports and land frontiers. At the Centre, in the Directorate General of Health Services the Government of India has appointed a Drugs Controller (India) who is also the licensing authority and is assisted by two officers, an Advisory Chemist and an Assistant Drugs Controller (India). At each of the ports of Bombay, Madras, Calcutta and Cochin an Assistant Drugs Controller has been appointed whose functions are (i) to control the quality of drugs; (ii) to ensure that the labelling and other provisions of the Drugs Act are followed by importers and (iii) to ensure that the importers of drugs requiring licenses possess the requisite storage facilities and take samples periodically or as often as they consider necessary and send them to a prescribed laboratory for test and report. These Assistant Drugs Controllers work in close liaison with the Customs authorities. The drugs which are found to be substandard are re-exported to the country of origin, if the defects cannot be remedied, or, alternatively destroyed. These officers have also been empowered to inspect periodically the premises, where imported drugs are stored and take samples therefrom to ensure that they have maintained their potency and strength. Batches of drugs, which are found to have lost their potency, are forced to be withdrawn from the market. The Assistant Drugs Controllers also advise the Customs Collectors, as well as the importers, on the provisions of the Legislation and the necessity for maintaining storage facilities for drugs imported.



**3.6. Control over Manufacture, Sale, and Distribution.**—Control on manufacture, sale and distribution of drugs is the responsibility of the State Governments. In all the Part A States and some of the Part C States, the Drugs Act has been enforced and a Drug Control Administration maintained for this purpose. But in most of the Part B States steps have yet to be taken to exercise this control. Sub-standard, adulterated and spurious drugs manufactured in States, where the control is yet to be exercised, often find their way into the States, in which the control is enforced and nullify its effects. Even in the States, where the Drug Control is in operation, it is not uniformly and effectively enforced. The Committee noticed during its visits that except in one or two States, the Drug Control Administration had been relegated to the background and was being treated as unimportant. The duties of the State Drugs Controller had been assigned to the existing Administrative Medical Officers like the Surgeon General or the Director of Health Services, who are already fully engaged with their duties and cannot be expected to spare sufficient time for this important work of drug control. In one of the States, this officer was also the Inspector General of Prisons. In making such appointments, the authorities concerned do not appear to have given due consideration to the scope, importance, technical nature and the type of work involved in the office of the Drugs Controller. To do justice to the work and be able to carry on the duties entrusted to them satisfactorily, the Drug Controllers both at the Centre and the States should be full-time officers and should have the following minimum qualification—

- (a) a Degree in Pharmaceutical Chemistry or Pharmacy or an Honours or post-graduate Degree in Chemistry;
- (b) an intimate knowledge of drug standards; and
- (c) adequate practical experience in the manufacture and testing of drugs.

This will ensure a more efficient administration of the Drugs Act. Hence statutory provisions should be made in the Drugs Rules.

**3.6.1. Administration of the Drugs Act** requires specialised knowledge. Training should, therefore, be provided under one of the Foreign Fellowship Schemes. At least two persons should be sent out for such training every year till an adequate number of persons is available.

**3.6.2. Some of the States** had appointed inspectors, who did not possess the qualifications laid down under the Drugs Rules. Even in the States, where it was better enforced, the number of Drug Inspectors appointed was inadequate. There are no proper testing laboratories to check the quality of products. Invariably, it was entrusted to the Public Health Department laboratories, where the analysts are very often only medical men, with no adequate knowledge and experience in the analysis of drugs. Complaints are frequently being received of varying analytical reports of the same products in the different testing laboratories.

3.7. In order to overcome these defects in the operation of the drug control existing at present, and to bring about a uniformity in the standards of products manufactured, we strongly recommend that the administration of Drug Control should be centralised by bringing control on manufacture, sale, and distribution, which is, at present exercised by the State Drugs Controllers, under the control of the Drugs Controller (India). This will help to bring about a uniform enforcement of the Drugs Act and a better co-ordination in the administration of the Drugs Act and the Industries (Development & Regulation) Act. The manufacturers, importers, medical men, retail traders and others interested in this industry have also unanimously represented through their respective organisations asking for a centralisation of the entire drug control administration in the country. As "Drugs" is a concurrent subject in the Constitution, we feel, that there will be no difficulty in the Central Government taking over control on manufacture, sale and distribution, which is, at present, exercised by the State Drugs Controllers and bringing it under the control of the Drugs Controller (India).

3.7.1. To enable the Drugs Controller (India) to take over the additional duties indicated in the preceding paragraph and also to further tighten up the existing control over imports, which he is already exercising, we recommend that the set up of the Drugs Control Administration at the Centre should be expanded on the lines given in Appendix No. 11. Once the Drugs Control Administration is centralised, it will require a department of its own in the Health Ministry.

3.8. The control over import of new drugs has been progressively tightened and now there are practically no cases where new drugs are allowed to be imported unless their therapeutic efficacy, pharmacological tests and standards are well established and approved by the Licensing Authority. The other condition is that before permission to import such drugs is given, evidence must be produced by the importer to the effect that such drugs are allowed free sale by the Health Authorities of the country of origin. No trials of new drugs are ordinarily allowed to be carried out in this country, unless the Licensing Authority is satisfied that similar trials have already been carried out in the country of origin. This precludes the possibility of the import of new drugs without clinical trials having been carried out in the country of origin. The standards of new drugs manufactured in this country have to be approved by the Central Government before they are allowed manufacture on a commercial scale.

3.9. To tighten up the control exercised by the Central Government on the entry of sub-standard, misbranded and adulterated drugs, it is necessary to provide adequate testing facilities and appoint additional staff at the ports. We, therefore, recommend the establishment of additional testing laboratories under the Drugs Control Organisation at the ports of entry for primary testing. This will obviate considerably, the delay which at present takes place in getting them tested at the Central Drugs Laboratory. To ensure that the importers have adequate facilities for the storage

of the drugs imported by them, additional staff to inspect their premises and take samples more frequently from their godowns is necessary. In the interest of efficient control on the imports of drugs, it is, therefore, necessary to provide for an adequate number of technical staff at the Centre and ports to help the Drugs Control Officers in their various duties.

#### 4. Facilities for testing drugs

4.1. *Central Government Laboratories.*—The present functions of the two Central Government Laboratories—the Central Drugs Laboratory, Calcutta, and the Central Research Institute, Kasauli have already been discussed. We visited these laboratories and studied their working during our itinerary in these places. The laboratories appear to be sufficiently equipped and adequately staffed for carrying out the duties entrusted to them at present. But with the centralisation of the Drugs Control Administration and improvement in the operation of the Drugs Control throughout the country, we envisage that the work of these laboratories will be greatly increased. Steps will, therefore, have to be taken to supplement the staff and testing facilities as and when the need arises.

4.1.1. During our visits, we noticed that the salaries of the Laboratory Assistants in the Central Drugs Laboratory, Calcutta, who actually carry out the analysis of the products were fixed at a very low scale of pay of Rs. 40—75 and Rs. 60—105. We found that many of them were graduates in science and were well-versed in analytical work. It is very unfair to expect men with such technical training to work on such low scales of pay, which are very nearly the same as paid to uneducated staff and be efficient. In view of the responsible nature of the work, we recommend that these scales should be revised to those paid to Laboratory Assistants in the National Laboratories of the Council of Scientific and Industrial Research, namely:

Graduates—Rs. 100—5—120—8—200—10/2—220.

Intermediates—Rs. 60—4—120—5—150.

Taking into account the importance of the work entrusted to them we also recommend that only graduates in Science should be recruited to these posts as and when vacancies occur.

4.1.2. Another discrepancy that we noticed in the scales of pay of the staff of this Laboratory was that the salaries of the Assistant-Chemists and Assistant Biochemists had been fixed in the scale of Rs. 160—330 while that of Assistant Bacteriologists and Assistant Pharmacologists in the scale of Rs. 160—450. We do not see the need for such a discrimination among the same category of staff, particularly as the same type of statutory work is performed by these people. We recommend that a uniform scale of pay of Rs. 160—450 should be given to all of them and the existing discrimination in their scales which adversely affects their efficiency, should be removed.

4.2. *State Government Laboratories.*—The following table indicates the laboratories and the designation of officers to whom the work of testing drugs has been entrusted by the State Governments:

**TABLE No. 34—GOVERNMENT ANALYSTS AND LABORATORIES NOMINATED BY EACH STATE ALONG WITH THE NUMBER OF INSPECTORS APPOINTED BY THEM FOR PURPOSES OF DRUG CONTROL.**

Name of the State	Designation of officers appointed as Government Analysts and Names of Laboratories.	No. of Drugs Inspectors.	Remarks
1	2	3	4
<b>PART 'A' STATES :</b>			
Assam.	Director, Bihar Drugs Control Laboratory, Bankipur, Patna. Director, Pasteur Institute, Shillong. Director, Haffkine Institute, Bombay. Asstt. Director, Haffkine Institute, Bombay. Associate Pharmacist, Haffkine Institute, Bombay.	1	While Director of the Pasteur Institute, Shillong has been appointed as Government Analyst in respect of certain items of Schedule C and C(1) products, officers of the Haffkine Institute, Bombay, have been appointed as Government Analysts in respect of the other Schedule C and C(1) products. For Drugs other than biological and special products, professors of the Chemistry Dept. of the Assam Medical College, Dibrugarh have been appointed as Government Analysts.
Bihar	Director, Bihar Drugs Control Laboratory, Patna.	Civil Surgeons of the State are ex-officio Drug Inspectors.	An Officer of Bihar Drugs Control Laboratory has been appointed as Government Analyst in respect of drugs other than those included in Schedule C and C(1). Officers of the Haffkine Institute, Bombay have been appointed as Government Analysts in respect of Schedule C and C(1) drugs as a temporary measure.
Bombay	The following officers of the Haffkine Institute, Bombay:— Assistant Director I/C of Pharmacology. Associate Pharmacist, Department of Pharmacology. Senior Organic Chemist, Department of Pharmacology.	20	

1	2	3	4
PART 'A' STATES— <i>contd.</i>			
	Senior Biochemist Department of Pharmacology.	}	
Madhya Pradesh	Officers of Haffkine Institute, Bombay.	1 All Civil Surgeons and Asstt. Surgeons are ex-officio drug inspectors.	Officers of the Haffkine Institute, Bombay have been appointed as Government Analysts for Schedule C and C (1) drugs.
Madras . (including Andhra)	Government Analyst Food and Drugs, King Institute, Guindy, Madras. Asstt. Director and Government Analyst (Drugs special) King Institute, Guindy Madras.	9	
Orissa .	Same as under Bombay.	1 Civil Surgeons are ex-officio Inspectors.	Officers of the Haffkine Institute, Bombay who have been appointed as Government Analysts for the State of Bombay are also Government Analysts for Orissa in respect of all kinds of Drugs.
Punjab .	Provincial Public Analyst and Officer-in-charge, State Drug Laboratory, Kasauli.	2 Asstt. Prof. of Pathology is Special Drugs Inspector (Ex-officio) for Biological products.	Officers of the Drugs Control Laboratory, Ambala Cantt. have been appointed as Government Analysts in respect of drugs other than biological and special products. Officers of the Haffkine Institute, Bombay, have been appointed as Government Analysts for Schedule C and C(1) products.
Uttar Pradesh .	Government Analyst U.P. Lucknow University, Lucknow	4	Public Analyst to the Government of U.P. appointed as Government Analyst under the Drugs Act in respect of drugs other than those included in Schedule C and C (1). Officers of the Haffkine Institute, Bombay have been appointed as Government Analysts for U.P. also in respect of Schedule C and C(1) drugs.

1	2	3	4
West Bengal	Government Analyst Provincial Drug Control Laby., School of Tropical Medicine, Calcutta.	6 (and 4 special Hon. Inspectors); (All Sub-divisional Health Officers are ex-officio Inspectors).	Director, West Bengal Public Health Laboratory is the Government Analyst for all drugs except Schedule C and C (1) products. No arrangement has yet been made for the testing of Schedule C and C (1) Drugs.
<b>PART 'B' STATES.</b>			
Ajmer	No appointment has been made so far.		
<b>PART 'C' STATES</b>			
Bhopal	Government Analyst State Laboratory, Putlighar, Bhopal.	1	
Bilaspur	Information not available.		
Coorg	Director, King Institute, Guindy, Madras.	1	The Government Analyst (Drugs) and Government Analyst Drugs (Special) of the King Institute, Guindy have been appointed as Government Analyst.
Delhi	Asstt. Director, Haffkine Institute, Bombay. ;	4	Officers of the Haffkine Institute, Bombay, appointed as Government Analysts for all classes of drugs.
Himachal Pradesh	Director, Central Drugs Laboratory, Calcutta.		Government of U.P. have agreed to the appointment of their Government Analysts as Government Analysts for Himachal Pradesh also in respect of drugs other than biological and special products. The Government of Bombay have been approached for agreeing to the appointment of their Government Analysts as Government Analysts for Himachal Pradesh also in respect of Schedule C and C (1) products.

1	2	3	4
Kutch . . .	No appointment has been made so far.		The Chief Commissioner has been advised to take up with the Government of Bombay the question of appointment of officers of the Haffkine Institute, Bombay as Government Analysts for Kutch also.
Manipur . . .	No appointment has been made so far.		Government of Assam have been requested to agree to the appointment of their Government Analysts as Government Analysts for Manipur also.
Tripura . . .	Information not available.		
Vindhya Pradesh	No appointment has been made so far.	8	Government Analyst is proposed to be appointed after a Notification is issued by the Central Government under rule 1 (3) of the Drugs Rule bringing the provision of the Rules in force in Part C States from a specified date.

4.2.1. It will be seen from the above table that one single laboratory—the Haffkine Institute—undertakes the work of drug analysis for several States, and the Government Analyst for Bombay State, has been appointed Government Analyst not only for Bombay State but for many other States. The names of different States and the class of drugs for which he is appointed as Government Analyst are summarised below:—

Name of State	Class of drugs for which appointed as Government Analyst.
Bombay . . . . .	(i) Biological and special products, <i>i.e.</i> , drugs included in Schedule C and C(1) of Drugs Rules 1945. (ii) Drugs other than mentioned in Schedule C and C (1).
Orissa . . . . .	Ditto
Delhi & Ajmer States . . . . .	Ditto
East Punjab . . . . .	Schedule C and C(1) Drugs only.
Bihar . . . . .	Ditto
C.P. and Berar (Madhya Pradesh) . . . . .	Ditto
Uttar Pradesh . . . . .	Ditto
Assam . . . . .	Ditto

4.2.2. The existing laboratory facilities for testing samples of drugs drawn by Drugs Inspectors are most inadequate in all the State Government Laboratories and result in inordinate delays. It is not uncommon to receive reports of analysis nine months after drawing the samples. To take action after a lapse of such a long period on stocks from which the sample was drawn is thoroughly impracticable. The inadequacy of Government laboratory facilities also restricts the number of samples drawn and analysed. The Chopra Committee had recommended, nearly 25 years ago, the establishment and maintenance of up-to-date laboratories in each of the States. We recommend an immediate implementation of this recommendation. It is also imperative that such laboratories should be well-equipped and adequately staffed to dispose of samples expeditiously. The drug control laboratories should be independent and should not form an appendage to Public Health, Food or Chemical Laboratories. The Heads of the Departments of these Laboratories should be sent for training in the U.K. or the U.S.A., in the latest technique of testing drugs and in this connection, the help of the World Health Organisation (W.H.O.), Technical Co-operation Mission (T.C.M.), and such other bodies should be sought. In examining the question of providing adequate laboratory facilities, advantage should be taken of such institutions as the Indian Institute of Science, Bangalore and the Central Drugs Research Institute, Lucknow. These Institutions have adequate equipment for testing of drugs and it should be possible for them to provide testing facilities to the States concerned.

4.3. *Manufacturers' Laboratories.*—A large number of drug manufacturers have their own testing laboratories. Whilst some of these are well-equipped and adequately staffed, a number of these are far from satisfactory and seem only to serve the purpose of "window-dressing". We have already recommended in the Chapter dealing with Small Scale Private Enterprise, a closer scrutiny of the equipment and testing facilities available, and the qualifications and experience of the staff employed before licensing the firms under the Drugs Act for the various products. We would also recommend that a frequent check of the records and test reports maintained in these laboratories should be made to see that their products are being regularly and properly tested.

4.3.1. Another suggestion to increase laboratory facilities for small scale manufacturers that we have recommended in the same Chapter is that a group of small medium sized manufacturers in various cities or localities should get together and set up joint laboratories on a co-operative basis. We feel that this would be the only way that the small manufacturers will be able to maintain a control on the quality of products made by them.

4.3.2. A number of witnesses have suggested that an organisation such as the Indian Chemical Manufacturers' Association, representing the Pharmaceutical Industry, should set up a control laboratory. One of the most important causes, if not the most important, which has impeded the growth and development of indigenous drug industry, is the lack of confidence among the medical men and also among the public in the products of indigenous manufacture. This Committee has repeatedly been told in most



emphatic terms by medical men, their Associations, Health Institutes, Defence Services and others, that Indian manufacturers have not yet succeeded in creating confidence in their products. Therefore, it is of primary importance that any step which may be taken to bring about this much needed confidence should be given top priority. The Committee recommend that medical profession and pharmaceutical industry should join together in setting up testing laboratories for the purposes of certifying the products made by the Industry, and thus create confidence among the public in the products manufactured. Such a procedure has been adopted in other countries with considerable success and a good example is the Institute of Hygiene, London. This Institute is entirely based on co-operative effort of member firms representing industry on the one hand and professional organisation on the other, and Government do not come into the picture so far as certifying the products is concerned. In this country, two organisations like the Indian Chemical Manufacturers' Association and the Indian Medical Association may well take up this joint effort. If any difficulty as regards finance is encountered, the Government should render assistance by way of grants or subsidies for testing laboratories of the type proposed above. Assistance may also be sought from International Organisations like W.H.O., T.C.M., U.N.I.C.E.F., etc. The Government should recommend such requests for assistance.

**4.4. Public Analytical Laboratories.**—There are at present a small number of Public Analytical Laboratories, approved by Drugs Controllers of different States, where, as provided in the Drugs Act, a large number of drugs are tested on behalf of those manufacturers who have no testing facilities of their own. The following laboratories may be mentioned:—

- (1) Italab Ltd.—with branches at Bombay, Calcutta, Madras, Nagpur and Vizagapatam.
- (2) Department of Chemical Technology, Bombay.
- (3) Therapeutic Research Corporation, Bombay.
- (4) Briggs Ltd., Calcutta.

These laboratories serve a very useful function and deserve to be encouraged. The confidence in the results of Public Analytical Laboratories in the country is of primary importance. The Drugs Control Authorities should keep a constant check on their activities and also verify the adequacy of equipment, staff and their technical competency.

**4.4.1.** When approval is given by the Drugs Controller to a manufacturer to have his products tested at one of the approved laboratories it sometimes happens, that adverse reports are not filed in the records and some machinery is necessary to prevent this practice, which could probably be obviated by insisting that a copy of each of the report may be sent direct to the Drugs Controller.

## **5. Menace of spurious drugs.**

**5.1.** The problem of spurious drugs has attracted country-wide attention again during the last two years. The menace began during the First World War, when India had to depend for all supplies of

drugs on other countries and unscrupulous elements in the drugs trade took advantage of the scarcity of essential drugs like Quinine, and marketed spurious products as genuine ones. This again reached prominence due to scarcity conditions produced during the Second World War. Even after the end of this War, the position has not improved and the spurious drugs trade flourishes to a colossal extent.

5.2. The spurious drug trade thrives due to several causes. First and foremost is the greed for making cheap money, taking advantage of the popularity of a drug by selling clever imitations as genuine products. The second cause is the tendency of the public to buy cheap drugs. The public in this country have yet to learn to buy their supply of drugs from licensed Chemists and Druggists instead of from general provision stores and grocers. A Chemist and Druggist has to keep an establishment in compliance with the various Laws viz. The Drugs Act, the Pharmacy Act, etc. He also buys his supplies from the manufacturers directly or from the authorised stockists and distributors. Other shops dealing in drugs buy their drugs usually from the middlemen or commission agents or as they are called 'walking chemists', who have no premises of their own and have no establishment to maintain. These are the persons, who are mainly responsible for the spurious drugs trade, because they sell spurious drugs at a rate, which is much lower than that supplied by genuine manufacturers to the general provision merchants and grocers, which ultimately is purchased by the lay public attracted by the difference in prices. The third cause is the shortage of medicines of established reputation. This shortage of medicines may be real, caused by restrictions in imports, or may be artificial, created by hoarding large stocks of drugs with the expectation that some day prices will rise further and benefit the hoarders. Another important cause is the high retail price of certain drugs such as the anti-biotics, viz. Chlortetracyclin, Oxytetracyclin, Aureomycin, Chloramphenicol etc., which are so much in demand due to their life saving property that the average public do not hesitate to buy them when their imitations are offered at lower prices, which spurious drugs manufacturer takes advantage of.

5.3. *Mode of Operations.*—The "modus operandi" in the manufacture of spurious drugs using genuine containers, labels and cartons is as follows: The genuine containers, etc. are collected by "Raddi Wallas" and are supplied in lots to the main shops, 'Jari Purana Wallas' etc. who deal in old bottles. The drug fakers obtain their supply from these dealers at regular intervals. The containers are purchased in a lot and deposited at some place. It is not an offence to have in possession any number of old containers. As soon as an order for spurious drugs is received, the containers are taken to the place, where the filling of the spurious drug is carried out. If a person manufactures these type of spurious drugs, it is neither an offence under the Indian Penal Code nor under the Trade Marks Act or Drugs Act because the drugs fakers never keep with them the dye or the instruments for counterfeiting the labels. His usual defence in a prosecution is that he is not manufacturing any faked drugs but he is having these for his own personal use as empty containers.

5.3.1. Labels of genuine drugs are also printed with the help of printing press owners who act as abettors and print these labels knowing full well that the person who has ordered them is not the genuine representative of the firm. Blocks for printing are destroyed on the spot, as soon as the order is executed. Thousands of labels are printed at one time, so that the question of printing afresh does not arise immediately. Thus, the chief evidence of counterfeiting is lost, although the printing press owner has committed a serious offence. These counterfeited labels are then stored with some relative or friend of the drug fakers, in order that such person might not at all be suspected. Just sufficient number of labels are taken to the place of manufacture, whenever required. If the printing block is not destroyed, it is also deposited in safe custody with some friend or relative. Manufacture of spurious drugs is carried out in unit operations. The raw materials which are used in these drugs (in case of solids it is generally chalk or sodium bicarbonate and in case of liquids, water mixed with some ingredients which smell and look as far as possible like genuine one) are stored at one place, and the place, where actual filling operation is carried out, is different from all the above three places.

5.3.2. These drugs, in turn, are passed on to the public through hawkers and walking chemists, who go from shop to shop and especially to grocers, restaurants, provision merchants and even to some unscrupulous chemists and druggists. These hawkers carry with them some fictitious cash memos and the same is tendered to the buyer. The buyer thinks that he will be protected, if the cash memo is produced. Sometimes, even medical men buy the drugs like Penicillin etc., from these walking chemists, because there is a great difference between the price quoted by them and by other retail dealers. Presumably, these walking chemists sell the goods with the plea that some firm has just gone into liquidation or that there is a general fall in prices. The walking chemists buy the empty vials and bottles and at times collect these from the compounders in hospitals and the same are given back to the manufacturers of faked drugs.

5.3.3. The evil of spurious drugs is in our opinion spreading throughout the country but in a few States due to the active work of the Drugs Control Administration, many cases have been brought to light and, therefore, it appears that it is most prominent in these States. In fact, the spurious drugs fakers have country-wide organisations, but it is most prevalent in Delhi, Calcutta, Bombay, Gwalior, Indore, some parts of Madhya Pradesh, Hyderabad and Saurashtra.

5.4. *Remedies.*—There is no doubt that the existing legislation is inadequate to fight the menace of spurious drugs and this is one of the main reasons, why spurious drugs are marketed on a large scale. The profit earned by the faker is so enormous compared to the punishment imposed, when convicted, that it is always an attractive proposition to manufacture spurious drugs. In a case reported from

Bombay, a person who was prosecuted for manufacturing spurious drugs jumped the bail and during the absconding period, he was again arrested for alleged manufacturing of spurious drugs. It can, therefore, be concluded that drug fakers are not deterred by the existing provisions of the law.

5.4.1 The amendments, that we have suggested to the Drugs Act further ahead in this Chapter will, we believe, set right such short comings in the existing legislation. A stricter and uniform enforcement of the Drugs Act with the suggested amendments will help to eradicate this menace to a large extent.

## 6. Industries (Development and Regulation) Act, 1951.

6.1. This Act, which came into force in 1951 gives Central Government powers to control Industrial undertakings of all the 42 industries scheduled in the Act, pharmaceutical industry being one of them. All the existing industrial undertakings, which come under this Schedule, are required to get themselves registered under the Act and obtain a licence before producing new articles. New undertakings have to obtain a licence before going into production. The Central Government has powers to investigate into the working of these factories, which come under the Schedule of Industries, revoke registration or licences and assume management or control of undertakings in certain cases. But the control on such factories is restricted to only those that come under the definition of a "factory" as given in the Act. A factory has been defined in the Act as consisting of 50 or more workers working with the aid of power or 100 or more without the aid of power. In the Pharmaceutical Industry out of about 1643 factories, only about 75 factories come under this definition. The value of products made by these 75 units amount to about Rs. 27 crores against a total production valued at about Rs. 35 crores by the entire pharmaceutical industry including Government Factories. Although a greater part of the industry's output emanates from the larger factories, the output of a large number of these small units, which concentrate mainly on one section of the industry i.e., processing pharmaceuticals into dosage form such as ampoules, tablets, capsules, compounded preparations etc. is substantial and cannot be ignored. There is also an economic justification for the existence of smaller factories in the pharmaceutical industry than those envisaged under the definition of a factory in the Act, as certain technical and highly specialised manufacturing processes are best operated in small specialised units.

6.2 As long as the small units conform to certain standards with regard to equipment, location, staff etc., they will be in a position to play an important part in the development of the industry. It is, therefore, necessary to bring such smaller units also under the purview of this Act and facilitate their development. To enable this, we recommend that the definition of a factory in the Industries Act as applied to the pharmaceutical industry should be amended to that given under the Factories Act, 1948 which is as follows:—

"Factory" means any premises including the precincts thereof:

- (i) Whereon ten or more workers are working, or were working on any day of the preceding twelve months and in

any part of which a manufacturing process is being carried on with the aid of power, or is ordinarily so carried on, or ;

- (ii) whereon twenty or more workers are working, or were working on any day of the preceding twelve months, and in any part of which a manufacturing process is being carried on without the aid of power, or is ordinarily so carried on,".

6.3. At present, there is a common set of Rules for all the 42 industries included in the Schedule of the Industries (Development & Regulation) Act. As the problems of the pharmaceutical industry are peculiar in some respects, a separate set of "Rules" for this industry should be prepared by modifying the existing Rules and/or incorporating new clauses wherever necessary, for the additional conditions mentioned in the succeeding paragraphs to be fulfilled.

6.4. *Co-ordination with Drugs Act.*—When a person intends to set up a pharmaceutical factory as defined in paragraph 6.2 above, he will have to apply to the Central Government for a licence under the Industries (Development & Regulation) Act, before setting up the factory or a manufacturing department necessary for the purpose. The Central Government will have to first investigate the advantages that can accrue to the public and the industry by undertaking such production in the quantity proposed, and after satisfying themselves, that it is in the interests of all concerned, give them necessary permission for putting up a factory. After the factory or manufacturing department has been put up, the manufacturer should apply for a licence under the Drugs Act. Permission to operate his factory and market the products should be given only after the Drugs Controller has scrutinised, and satisfied himself that the manufacturer has the minimum requirements of equipment, qualified personnel, premises, sanitary conditions etc. which the Committee have already specified. The licence under the Industries (Development & Regulation) Act should, therefore, be granted subject to the manufacturer obtaining a licence under the Drugs Act. There should be a perfect co-ordination between the licensing under the Drugs Act and the licensing under the Industries Act. Licences will have to be issued under the respective Acts only after consultation between the two concerned Departments of Government.

6.4.1. While on this subject we would like to emphasise that such co-ordination will be greatly facilitated, if the enforcement of the Drugs Act is centralised which we have recommended already. During our visits to the different parts of the country and discussions with the drugs controlling authorities, we have found, that there are serious differences in the interpretation and the methods of administration of the Drugs Act.

6.4.2. In very many States, the Drugs Act is so poorly administered that we found that factories, which had been licensed were located in insanitary places and their premises maintained in no better condition. They also had no proper equipment for manufacture or testing, and neither the manufacturers nor the State were exercising any control on the quality of the products made by them. The products of these factories were a menace not only to the particular

State, in which they were located, but also to the neighbouring States, to whose market they found their way. The people of the neighbouring States were in no way benefitted in spite of the fact that the Act was being administered there in a better manner. When these points were brought to the notice of the State Drugs Controllers, they appeared to be helpless in the matter, either because they were afraid that by closing down such factories, it might lead to unemployment, labour unrest etc., or they had their own misgivings of the powers delegated to them under the Drugs Act to take such steps. It is, therefore, necessary to centralise the administration of the Drugs Act to bring about a uniform implementation of the Drugs Act throughout the country for proper co-ordination with the working of the Industries (Development & Regulation) Act to be possible.

6.5. *New grouping*.—The firms should be licensed to manufacture drugs under the Industries (Development & Regulation) Act according to any of the two groupings given in the classification in Lists A & B of the following table:

TABLE NO. 35  
CLASSIFICATION OF PHARMACEUTICAL PRODUCTS  
LIST A

1. *Galenicals*.
2. *Anti-Allergic Preparations*.
3. *Anti-biotics*.
4. *Analgesics and anti-pyretics*—e.g. Opium and morphine Preparations, Para-aminophenol derivatives, Pyrazolon derivatives e.g., amidopyrine, Salicylic acid compounds, Cinchona alkaloids and Synthetic anti-malarials.
5. *Anaesthetics*.
6. *Anti-infectious (other than anti-biotics)*.
  - A. *Local*—e.g. Anthracene derivatives, phenol, cresol and derivatives, dyes, Furan derivatives, halogen compounds, metal, compounds, Sulpha-drugs, etc.
  - B. *Systemic*—e.g., Chaulmoogra derivatives, Cinchona alkaloids and Synthetic antimalarials, Metallic compounds, Hydroxyquinoline derivatives, Anthelmintics, anti-tubercular drugs.
7. *Antispasmodic preparations*.
8. *Astringents*.
9. *Anti-tubercular preparations*—e.g., PAS Salts, Isonicotinic acid hydrazide.
10. *Autonomic Drugs*—e.g., Amphetamine preparations, Ephedrine preparations, adrenaline preparations, Atropine derivatives and analogues.
11. *Cardio-Vascular Agents*—e.g., Digitalis principles and preparations, Strophanthine, Squill preparations, Quinidine.

12. *Diuretics*—e.g., Mercury compounds, Urea and Xanthine derivatives.

13. *Gastro-intestinal Drugs*—e.g., Antacids, Choleric, Demulcents, Emollients, Laxatives.

14. *Hemetics*—e.g., Anticoagulants such as Dicoumarol, Heparin, Iron and Iron compounds, Brain preparations, Haemostatics such as cyano-cobalamin, Liver preparations, Stomach preparations.

15. *Hormones & Synthetic Substitutes*—e.g., Adrenals, Ovarian preparations and Estrones, Corpus Luteum hormones, Insulin, Pituitary, Thyroid and parathyroid preparations, Testicular preparations and Androgens.

16. *Agents used in Metabolic Disorders*—e.g., Proteins and Amino-acids, Dextrose, Calcium-salts, Lipotropic agents e.g. Choline salts.

17. *Oxytocics*—e.g., Ergot Preparations.

18. *Parenteral solutions*.

19. *Sedatives and Hypnotics*—e.g., Bromides, Chloral derivatives, Hydantoin derivatives, Oxazolindine derivatives, Sulphonals, Barbiturates, Morphine Group, Pethidine.

20. *Vaccines & Sera, Toxins, Antitoxins, Toxoids*.

21. *Vitamins and Vitamin Preparations*.

22. *Unclassified Therapeutic Agents*.

NOTE:—(i) Classification in Group A is of necessity made on very broad lines and indeed it must be so kept so as to give a fair amount of latitude to manufacturers.

(ii) In this classification a certain amount of overlapping is unavoidable due to multiple uses of one and the same drugs.

(iii) Parenteral solutions have been included in Group A and not in Group B because the plant and equipment for manufacture of injectibles is rather costly and most of the manufacturers have great difficulty in utilising their installed capacity economically. It is, therefore, felt that restrictions may be placed on the manufacture of injectibles.

#### LIST B

(a) *Liquid preparations*: (i) local such as Lotions and Liniments, Inhalations, Drops and Sprays; (ii) for internal administration, Elixirs, Mixtures, Solutions and Syrups.

(b) *Granules, Powders, Tablets, Pills, Capsules, Cachets*.

(c) *Lozenges and Pastilles*.

(d) *Bougies, Pessaries, Suppositories*.

(e) (i) *Ointments and Pastes*:

(ii) *Emulsions & Suspensions*.

**NOTE:—**The main basis of classification in Group B is the plant and equipment required for each group. Thus, more or less same plant and equipment is required to manufacture tablets, pills or granules, or again to manufacture ointments and emulsions or again mixtures, elixirs or syrups.

6.5.1. For example, a factory licensed to make products which come under List [A(2) and List B(b)] should be free to make all products, which come under Anti-Allergic preparations [List A(2)] in the form of tablets, pills, granules, powders, capsules cachets [List B(b)]. It will be only if the firm wants to make any product that does not come under the grouping for which it has been licensed, that it will have to obtain permission of the authority exercising the Industries (Development & Regulation) Act for the new grouping under which this product falls.

6.6. *Development Council for Pharmaceuticals and Drugs.*—To ensure future development of the pharmaceutical industry on the lines of our recommendations, immediate steps should be taken by Government to constitute a Development Council for Pharmaceuticals and Drugs. This Council should be under the Ministry of Commerce and Industry and it should include:—

- (1) The Industrial Adviser (Chemicals);
- (2) The Drugs Controller (India);
- (3) Representatives of the Industry;
- (4) Representatives of consumers who in this specific industry are medical men; and
- (5) Representatives of the pharmaceutical trade viz., distributors, wholesale and retail pharmacists.

Adequate functions should be assigned to the Council for implementing the recommendations of the Committee. For carrying out these functions, sufficient technical and secretarial assistance should be given.

## **7. Amendments to the Drugs Act and the Rules thereunder.—**

7.1. In addition to centralising the Administration of the Drugs Act, it is necessary to bring about certain changes in the Act and the Rules thereunder for (i) having a more effective control on the quality of pharmaceuticals, and drugs produced and marketed in the country; (ii) bringing about a better co-ordination with the working of the Industries (Development & Regulation) Act, and (iii) eradicating the existing menace of sub-standard and spurious drugs. The Act and the Rules thereunder should, therefore, be amended to provide for the following conditions:—

7.1.1. The term “manufacture” should be defined for the purposes of this Act as under:—

“‘Manufacture’ in relation to any drug includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution but does not include the compounding or dispensing or the packing of any drug in the ordinary course of retail business.”



7.1.2. The term "Drug" should be defined on the lines of the Federal Food Drugs and Cosmetics Act of the U.S.A. This definition is reproduced below:—

"The term 'drug' means: (i) an article recognised in the Official United States Pharmacopoeia or Official National Formulary or any supplement to any of them; (ii) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (iii) Articles (other than food) intended to affect the structure or any function of the body of man or other animals."

Adoption of such a clause will bring disinfectants, insecticides and contraceptives and the standards for such disinfectants, insecticides and contraceptives, as would be prescribed, under the purview of the Drugs Act.

7.1.3. At present there is provision for the marketing of proprietaries with secret formulae after registration in the Central Drugs Laboratory. This provision should be withdrawn and no patent or proprietary preparations with secret formulae should be allowed to be marketed. Any product to be marketed must have its composition and method of usage published on its label.

7.1.4. Offences under the Drugs Act for trading in spurious and sub-standard drugs should be made cognisable. A deterrent punishment with adequate fine and a compulsory period of rigorous imprisonment should be given.

7.1.5. Giving of adequate publicity of the offender's name and address should be made compulsory.

7.1.6. The trading licence of such an offender should be cancelled and it should be made impossible for him to restart the trade either in his own name or in partnership with others. It is only such deterrent punishment and adequate publicity that will put an end to the trading in spurious and sub-standard drugs, which is so prevalent.

7.1.7. In cases, where a licence has been suspended for the contravention of clauses dealing with trading in spurious and substandard drugs, irrespective of the particular licence to which the offence relates, all other licences should also be suspended for the period and the establishment forced to remain closed.

7.1.8. Suspensions should ordinarily be not given in case of technical offences like non-maintenance of records etc. which should normally be punished by fine unless these offences have been recurring often.

7.1.9. It has to be pointed out that, at present, the possession of spurious drugs is not an offence until the sale of such a drug is effected. Therefore, the possession of spurious drugs should also be made an offence under the Drugs Act.

7.1.10. The possession of any die, plate or other instrument for the purpose of counterfeiting any label or wrapper of a drug, or the

possession of a trade mark or proprietary mark for the purpose of falsely denoting that any drug is the manufacture or merchandise of a particular person or firm, should also be made an offence. The punishment should be either imprisonment extending upto a period of three years or a heavy fine or both.

7.1.11. The provision, whereby an Inspector has to take the permission of a District Magistrate or the Chief Presidency Magistrate for search or seizure of adulterated or misbranded drugs should be deleted.

7.1.12. To safeguard the interests of the public against the unsuitable and harmful formulations, sections 12(m) and 33(k) of the Drugs Act should be made applicable to all formulations of drugs and medicines sold in the country.

7.1.13. Minimum requirements of premises, sanitary conditions, equipment and qualified personnel for the manufacture of different products, as indicated by us in Chapter II dealing with Small Scale Private Enterprise, should be specified in the Rules under the Drugs Act.

7.1.14. No license for the manufacture of pharmaceuticals should be given unless the conditions regarding minimum requirements are fulfilled. Licences for the existing factories that do not fulfil these conditions should be revoked.

7.1.15. The Rules under the Drugs Act prescribe the following licence fees for importing, stocking, exhibiting, selling and manufacturing of drugs and medicines:

*Form 10.*—Licence to import biological and other special products specified in Schedules C and C1 to the Drugs Rules—Rs. 10 for two years.

*Form 20.*—Licence to sell, stock and exhibit for sale, and distribute drugs other than biological and special products specified in Schedule C—Rs. 5 for two years.

*Form 21.*—Licence to sell, stock and exhibit for sale and distribute biological and special products specified in Schedule C—Rs. 5 for two years.

*Form 25.*—Licence to manufacture drugs other than biological and special products in Schedules C and C1—Rs. 20 for two years.

*Form 28.*—Licence to manufacture biological and other special products specified in Schedules C and C1—Rs. 20 for two years and an inspection fee of Rs. 100 at the time of application for licence.

In order to prevent the unhealthy competition in the profession which has been flooded by unqualified people as a result of charging such low fees, we feel, that the fees for the above licences should be revised and increased as indicated below. While making it clear that the fees should not be viewed as a source of revenue, Drug Control being a social legislation, it is considered that the revenue from an increase in the fees will meet part of the expenditure that has to be incurred for an efficient administration of the Drugs Act as suggested:

**Form 10.**—The fee for an import licence for the import of any biological or other special products specified in Schedules C and C1 should be Rs. 200 for two years with an endorsement fee of Rs. 100 per endorsement.

A licence fee should be imposed for the import of products not specified in Schedules C and C1 at the rate of Rs. 50 per two years for each manufacturer abroad, a separate licence being given for each manufacturer.

**Forms 20 and 21.**—Licences for stock and sale of drugs should be in two categories and no trader should be allowed to trade both as a wholesaler and retailer in the same premises. Separate licences should be obtained if the same person sets up business both as a wholesaler or a retailer.

In the case of wholesalers, there should be two categories of licences:—

(a) *A distributor for a limited number of manufacturers and importers:*

A fee of Rs. 500 for 2 years should be charged for one or more groups of manufacturers provided he does not represent more than 10 manufacturers. For every additional manufacturer whom he represents, a fee of Rs. 100 for 2 years should be charged.

(b) *A general wholesaler who deals in all types of drugs and medicines from all importers and manufacturers:*

A fee of Rs. 1,000 for 2 years should be charged.

The above scale of fee for distributors should not vary, wherever they are situated, within the territory in which they operate, but for wholesalers who are not situated in big towns like Bombay, Calcutta, Delhi and Madras, the fee should be as follows:—

Cities with a population of	Fee for 2 years. Rs.
55,000 and under . . . . .	5
5,000 to 50,000 . . . . .	20
50,000 to 100,000 . . . . .	50
100,000 to 500,000 . . . . .	100
500,000 and above . . . . .	200

In cities of Bombay, Calcutta, Delhi and Madras, the fee for a retail licence in Forms 20 and 21 should be Rs. 500 for 2 years for each. For other cities, the same scale of fee mentioned above for wholesalers, should be charged.

**Form 25.**—A manufacturing licence for drugs other than biological and special products should be Rs. 1,000 for 2 years initially; and for every new product endorsed, it should be increased by Rs. 50 subject to a maximum of Rs. 2,000 for 2 years.

*Form 28.*—Licence fee for the manufacture of biological and special products should be a minimum of Rs. 2,000 with an endorsement fee of Rs. 50 per item subject to a maximum of Rs. 4,000, for 2 years.

The inspection fee should be Rs. 250 for the first inspection before the grant of a licence and Rs. 150 for every subsequent inspection at the time of renewal.

The inspection of a factory for the manufacture of products specified in Schedule C and C1 of the Drugs Rules should be conducted by a panel of experts at least one of whom shall be a person suitably qualified for such inspection.

The licence issued for manufacture will include the licence for sale by way of wholesale transactions from the factory. If, however, the factory has a separate place where manufactured goods are stocked and sold in the same town, such premises should be licensed as a wholesale distributor. Normally no manufacturer should be allowed to act as a distributor also. Established traders should be encouraged to act as distributors.

7.1.16. Quite a number of pharmaceutical firms do not possess an equipped factory of their own but still market pharmaceutical products by getting their products manufactured in any of the well-equipped and well staffed factories, under the system commonly known as "Loan Licensing". Inasmuch as the country at present possesses more than ample processing capacity this system of loan licensing could be adopted for utilising the surplus capacity. For some time at least this loan licensing system will be necessary. It is recommended that the fee for such loan licences should be Rs. 400 for two years and permission for manufacturing new products should be endorsed on such licence, each endorsement being charged Rs. 20 for two years.

7.1.17. For the proper development of the Pharmaceutical Industry, it is necessary to see that the quality of the crude drugs used as raw material should be ensured. At present, these are handled by people who are not qualified by education or training to do so. In order to improve the quality of the crude drugs available in the market, dealers of such drugs and their premises should be licensed and limited to those who are in a position to guarantee their quality to the manufacturers, and exporters.

7.1.18. It should be made compulsory that every licensed dealer in such drugs should give a warranty about their active constituents.

7.1.19. Manufacturers who obtain their crude drugs requirements directly should license themselves as dealers in crude drugs.

7.1.20. A licence fee of Rs. 100 for 2 years for such registered dealers should be imposed and provision for this made in the Drugs Rules.

7.1.21. Rule 109(1)(a), which reads as follows, is at present applicable to Schedule C drugs. This Rule should be made applicable to all drugs and rigidly enforced. It should apply, in addition to the labels on the containers, to advertisements in Medical Scientific and Trade Journals and the literature distributed by the medical profession and chemists and druggists.

**"Rule 109(1) (a): Labellings:—**(1) Every phial, ampoule or other container of a substance specified in Schedule C shall bear a label on which is printed or written in indelible ink the following particulars and such further particulars, if any, as are specified in Schedule F:—

- (a) The proper name of the substance in letters not less conspicuous than those in which the proprietary name, if any, is printed or written and following immediately after or under such proprietary name."

7.1.22. In the case of combinations, the names of the main ingredients should be displayed in letters of readable size on the labels of the containers and in the advertisements and medical literature.

7.1.23. Sufficient number of well-qualified and properly paid Inspectors should be appointed so that the premises of drug manufacturers, distributors and traders may be more frequently inspected and samples drawn and tested.

7.1.24. The scales of pay of Inspectors should be uniform throughout the country and should start with a minimum of Rs. 275 per mensem. One Inspector should be appointed for not more than 200 selling premises or for not more than 100 manufacturing premises, so that every shop or factory could adequately be inspected.

7.1.25. The Committee has observed that sufficient staff is not provided in many Government Testing Laboratories. They should, therefore, be adequately staffed and the Government Analysts appointed should possess special qualifications in Chemistry in addition to sufficient experience in the modern technique of drug analysis.

7.1.26. The problem of the re-use of old containers has assumed serious proportions. Wide publicity for this is required and the co-operation of the public, the medical profession and chemists and druggists should be sought for the prompt destruction of such containers and thus prevent them from falling into the hands of unsocial elements. Documentary films, cinema slides and posters should be used for giving wide publicity to check this malpractice.

7.1.27. Chemists and Druggists should organise themselves and advertise in the leading professional and Trade journals and newspapers that quality drugs can be had from their Member-Firms who should be made to display, in a prominent place of their shop a badge distributed by the Association. The advertisements should state that the prices of drugs sold by such firms are the fair prices. Such propaganda will not only induce all the chemists to join the Association but also infuse into the minds of the public a sense of confidence in the quality of drugs sold by such dealers.

7.1.28. The use of pilfer-proof closures should be strongly encouraged, and for certain drugs, their use with a seal or stamp should be made obligatory.

## CHAPTER VI

### RESEARCH WORK

#### 1. Research Work in Europe and America:

1.1. Many fruitful discoveries, in the field of therapeutics, have taken place during the last few years in the continents of Europe and America. Mention may be made of the anti-malarials—(Pamaquinum (B.P.) (Syn. Plasmochin), Mepacrinae Hydrochloridum (B.P.) (Syn. Atebrin), Proguanil Hydrochloridum (B.P.) (Syn. Paludrine); the antibacterials—(Sulphonamide group); remedies for the treatment of shock (Blood Plasma and Sera); specific remedy for the prophylaxis and treatment of Measles (Gammaglobulin), the insecticides (D.D.T. and B.H.C.); and the antibiotics (Penicillin, Streptomycin, Chloramphenicol, Chlortetracyclin, Erythromycin).

1.2. It is interesting to note, that during the War years inspite of the then prevailing unsatisfactory conditions the maximum number of discoveries were made in the realm of drugs. It is significant that, whereas most of the earlier discoveries of this century such as Salvarsan and Bayer 205 came from Germany, considerable contributions have also been made by America, Great Britain and Switzerland to the later ones. The time lag between the laboratory discovery of a drug, its manufacture, and its clinical application has been particularly short. The leadership of Germany in the field of discoveries in synthetic and chemotherapeutic remedies during the early part of this century was due primarily to its having a large dyestuff industry with highly trained chemical staff, and secondly to the collaborative efforts between chemists and medical men. This was in sharp contrast to the individualistic methods of investigation, which were in vogue in the 19th and early 20th centuries in other countries. It was clearly recognised early in Germany and later in England, America and Switzerland, that creative drug research was essentially the collaborative efforts between different groups of scientific workers. There are but few individual workers, who possess all the technical skill and theoretical knowledge required for the development of the whole field of drug and pharmaceutical research.

#### 2. Research work in India:

2.1. *General.*—If India is to solve her difficulties in the field of health and sanitation, it is imperative that drug research should be well organised in a way similar to that in the United Kingdom, America, Germany and Switzerland. Intensive research in Drugs and Pharmaceuticals is an essential part of any health plan for our country. The vastness of the problem can well be judged from the enormous amount of sickness and high death rate that prevails here. Much work on indigenous drugs has been done in India during the

last 25 years, Col. R. N. Chopra being a pioneer in this field. Valuable investigations were conducted under the Indian Council of Medical Research, and Institutions like the School of Tropical Medicine, Calcutta, the Haffkine Institute, Bombay, Indian Institute of Science, Bangalore, Central Research Institute, Kasauli, certain universities like Delhi, Andhra, Benaras, Calcutta etc. Lately under the auspices of the Council of Scientific and Industrial Research useful work has been done specially at the Central Drug Research Institute, Lucknow. Much of this work, however, was not of an intensive nature and co-ordinated investigations embracing chemical, pharmacological and clinical aspects of drug research have been rare. This lack of collaborative effort between various groups of scientists engaged in research and those engaged in the industry, has been one of the major factors responsible for the present unsatisfactory position in drug research and drug industry in India. Only in a few Government Institutions, collaborative effort between chemists, pharmacologists and bacteriologists is discernible; but the lack of co-operation between scientific men at the Universities, members of the medical profession and the technical personnel in manufacturing concerns, has been marked—the former usually confining themselves to problems of academic interest and the latter pursuing only well-known and commercially profitable lines.

2.2. Drug and pharmaceutical research, comprehensively considered, has very wide scope in India. It will extend from systematic scientific study of the crude drugs that have been used in the indigenous system of medicines for centuries, on the one hand, to the highly developed field of synthetics and antibiotics, on the other. Nearly 75 per cent. of the drugs of vegetable origin listed in the British Pharmacopoeia are native to India and suitable substitutes for a large number of others can easily be found. Much of India's drug resources are still unexplored and unexploited.

2.3. While the pre-war studies and methodology of research was based primarily on physiological and pharmacodynamical technique, more emphasis is now being laid on the study of pharmacological problems through biochemical routes. In all advanced centres of Medical Research, studies in cell morphology, endocrinology and tracer technique are coming to the forefront. In fact, the base of operations has shifted from pure pharmacodynamical studies to investigations on enzymes, mechanism of action of hormones, metabolism of parasites responsible for the various diseases, processes of absorption, excretion, depot formation, cell permeability etc. If creative research on an international level is to be done, pharmacological work in India has to be aligned along these lines.

2.4. Pharmacological, chemical and clinical investigations involve the isolation, and purification of the active principles present in the drugs followed by thorough pharmacological examination. The physiologically active principles indicating good prospects of use as medicines are subjected to clinical trials after determination of the toxicity. As a result of these trials several preparations of useful drugs from indigenous plants are already available in the market, and some of them have been very popular and are extensively used; the extract of *Rauwolfia serpentina*, as an effective remedy in

hypertension, is one of them. In reviewing the research work done in pharmacology and allied subjects in India it is not the intention of the Committee to submit a complete or chronological account of all the investigations in indigenous and other drugs, which have been carried out here. The Committee do believe, however, that the growth of pharmaceutical industry in this country is closely linked up with the expansion of drug research, to which we attach great importance. Our intention is to give a brief account of some of the research work done hitherto. This will serve as a background to the problem as it exists today, and to indicate the directions, in which further progress should be made.

*2.5. Research Work by Government Institutions and Universities.*—Among the researches carried out under the auspices of the Indian Council of Medical Research (I.C.M.R) and the Council of Scientific and Industrial Research (C.S.I.R.) special mention may be made of the work done on the indigenous drugs of India. These were undertaken with the following main objectives:—

- (i) to make India self-supporting by enabling her to utilise the drugs available in the country by manufacturing them in a form suitable for administration;
- (ii) to discover remedies from the claims of Ayurvedic, Tibbi and other indigenous systems suitable to be employed by the exponents of modern medicine; and
- (iii) to discover the means of effecting economy, so that these remedies might fall within the reach of the great masses in India, whose economic condition is very low.

The details of the research work done under the auspices of the C.S.I.R. and I.C.M.R. are given in appendix No. 12.

*2.5.1.* Very notable contributions have been made by Col. R. N. Chopra and his co-workers in this field. As a result of these investigations, the utilisation of a large number of drugs like Aloes, Artimesia, Ephedra etc. which grow wild and in great abundance in this country, and which are known in Indian and modern medicine has become possible. A number of pharmacopoeial drugs, which are widely used by the medical profession, but which do not naturally grow in India like Digitalis, ergot and Ipecac have been introduced, and found to thrive well, when cultivated under proper conditions in certain parts of the country. A large number of plants, which grow in India, and which can form excellent substitutes for the imported and often expensive remedies, have been made available for use. Frequently, these are closely allied species, which are pharmacologically just as active as the imported varieties like *Colchicum luteum* for *C. autumnale*, *Scilla indica* for *Urginia maritima*, *Picrasma Quassoides* for *Picroena excelsa*, etc. A considerable amount of work has been undertaken to determine the active ingredients of these drugs, their composition and pharmacological action, by various university laboratories in the departments of chemistry and pharmaceuticals, the School of Tropical Medicine, the Haffkine Institute, the Drug Research Laboratory, Jammu etc. Pharmaceutical preparations of active principles from these sources are now being

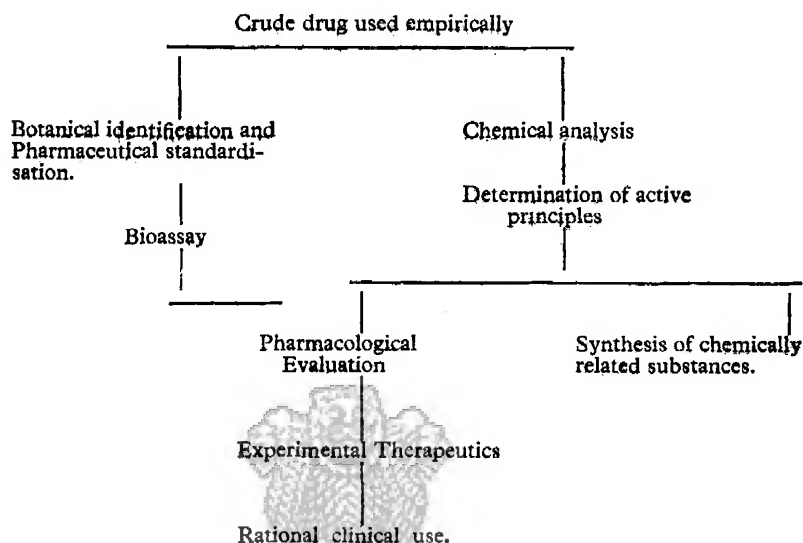


manufactured as a result of these investigations by most manufacturing concerns. Data with regard to about 180 items has been published by the Government of India in the Ministry of Health as the first Indian Pharmacopoeial List. It is a book of standards for Indian drugs and has the same status in India as the British Pharmacopoeia. From this nucleus, a Representative Committee under the Health Ministry has compiled the first Indian Pharmacopoeia. The standards and tests provided therein will take into consideration the nature of the products that are likely to be obtained by starting from indigenous sources. It may be mentioned here that very often the drugs made from indigenous sources are not able to fulfil the requirements specified in the British and other Pharmacopoeias, although these preparations are equally efficacious in the treatment of diseases. This drawback will be obviated with the coming into use of the Indian Pharmacopoeia. In addition, an Indian Pharmaceutical Codex provides 193 monographs and a Formulary giving pharmacognostic, chemical, pharmacological and therapeutic data on indigenous drugs with their preparation and dosage for the use of medical and pharmaceutical professions. Efforts are being made to bring them into use in the treatment of minor maladies. These standardised indigenous drugs, which will be equally efficacious for symptomatic treatment are expected to make the country entirely independent of imports of many simple proprietary preparations.

2.5.2. The work of discovering remedies from the claims of Ayurvedic and other indigenous systems of medicine for their use in modern medicine has been a more difficult task. Many of the effective remedies of the Indian systems of medicine appear to have been lost and increasingly replaced during the period of their decay by many useless substitutes. Almost every plant and shrub grown in the country has been ascribed some medicinal virtue. The remedies have multiplied without proof, and as they come from all parts of India, no one seems to have a correct opinion about their uses and properties. The employment of a large number of them would thus appear to have been based on empirical knowledge handed down from generation to generation. Before a crude drug can be used in rational scientific medicine, it has to pass through long and tedious processes like (i) botanical identification, (ii) chemical examination, (iii) pharmacological and toxicological assay, (iv) chemo-therapeutic, and (v) clinical trials. A screening of these innumerable drugs that are now being claimed to have therapeutic properties would constitute the life-work of many chemists,

pharmacologists and clinicians. The following schematic programme shows the rational procedure adopted at present for the evaluation of these drugs:—

*Schematic Programme necessary in the Evaluation of drugs.*



These investigations also require team-work by several groups of scientists, each an expert in his own field. The facilities for such team-work are not easily available in the country. With the setting up of research laboratories by Government Institutions, Universities and manufacturing concerns, such work becomes more possible and must be actively encouraged. Many research laboratories in other countries have taken up the intensive study of Indian drug and achieved remarkable results. These investigations have brought into prominence the merits and qualities of certain drugs such as *Holarrhena anti-dysenterica*, *Rauwolfia serpentina*, *Adhatoda vasica*, etc., etc. *Holarrhena* (Kurchi) has come to stay as an excellent remedy in certain acute cases of dysentery. Standardised liquid extract of this drug and the preparation Kurchi Bismuth Iodide have come to be accepted as recognised remedies and were largely used in the theatres of war in the near and Far-East with satisfactory results. *Rauwolfia*, which is a very old drug used in the Indian systems of medicine, has now come to be recognised as one of the best remedies for the treatment of hypertension.

2.5.3. Another difficulty, that comes in the way of investigating Indian drugs is the problem of correct identification. Many of the remedies mentioned in the old texts cannot be easily recognised and identified as the descriptions given are not very complete. This has resulted in a good deal of confusion and even experienced workers are not able to recognise with certainty the authentic specimen mentioned in old texts. To overcome this difficulty, a systematic pharmacognostic study of Indian drugs has been undertaken to help correct identification of medicinal plants.

2.5.4. The improvement of economic plants, for better yield of active principles is a very rich field for investigation, which still remains largely unexplored in this country. Grafting, selection, hybridization, induction, of mutagenic variants by radiation and chemical agents, and production of polyploidy by colchicine treatment are some of the methods that have been successfully employed in this direction in other countries. But in India, this is only at a very preliminary stage and has to be encouraged for improving the varieties, that are now being cultivated.

2.5.5. The present growing interest in medicinal plants, which grow wild in India like *Rauwolfia*, which have shown promising therapeutic properties has created indiscriminate exploitation of these plants which will lead to their complete annihilation. To maintain their regular supply, their indiscriminate exploitation should be stopped.

2.5.6. Experimental farms should be set up to determine the best seasons for cultivation and collection of medicinal plants. Based on this information, large scale farms should be established to ensure regular supply.

2.5.7. Several Universities are conducting research in pharmaceutical and related biological subjects. These are the universities of Andhra, Benaras, Bombay, Calcutta, Delhi, Gujrat, Madras etc. Other institutions like Veterinary Research Institute at Izzetnagar (U.P.), Central Research Institute, Kasauli, King Institute, Guindy (Madras) and Haffkine Institute at Bombay and Pasteur Institutes located in different parts of the country are doing very useful research work in the field of biologicals, although their main concern relates to the manufacture of sera and vaccines. Among these may be mentioned the successful production of polyvalent and divalent antivenine Sera, which are antidotes against bites of different species of poisonous snakes; research on the production of the hyper-immune rabic serum for the treatment of rabid dog bites to obtain cent per cent success, which is not guaranteed, at present, with the use of the ordinary antirabic vaccine; and research for the production of whooping cough vaccine, which is being mainly imported at present into the country. The Haffkine Institute at Bombay also has been active in the development of modern remedies like sulphadiazine drugs and other chemotherapeutic products.

2.5.8. From the above, it can be concluded that a number of trained personnel and some tradition for pharmaceutical investigations has thus been made available. But what has been achieved is not by any means adequate for the needs of the country and the development of the industry.

2.6. *Research Work by Medical Colleges.*—Out of the 32 medical colleges, which replied to the questionnaire issued by the Committee, it is noticed that research in pharmacology is undertaken only in 20 medical colleges. A few medical colleges also undertake research in Biochemistry. The staff employed is inadequate from several points of view.

2.6.1. Lack of adequate equipment for undertaking satisfactory pharmacological and biological investigations of drugs in most of the

medical colleges and pharmacy departments of the universities is also a serious handicap awaiting prompt rectification. Most of the colleges have complained of inadequate finances. It is a fact that research in pharmacology is lagging behind chemical research at the present time and this is one of the factors which prevents the development of chemical research in the field of drug industry. This should be overcome by providing more adequate personnel, equipment and finances for research work in medical colleges.

2.6.2. A survey of the research papers on pharmacological and allied subjects published in the recognised journals during the period 1944-52 indicates that there have been even fewer publications than during the previous corresponding periods. This paucity is due to lack of adequately trained personnel and this situation requires immediate attention. Consequent upon the opening of a number of new medical colleges, departments of pharmacological research, laboratories of well-known commercial organisations, as well as absorption of research personnel by overseas fellowships and scholarships under various schemes, there is a great demand for larger number of trained pharmacologists.

2.6.3. In order to provide the required number, it is not sufficient to train only medical men in pharmacology. Training should be thrown open to Chemists and Biologists, who will stick to this subject without being attracted by better remuneration in the medical field. It is quite essential that special scholarships should be granted for training in this particular subject. To overcome this handicap at present felt for lack of adequate equipment and funds for undertaking research in pharmacology by the Medical Colleges, we recommend that these institutions should also be given substantial grants by the Central and State organisations sponsoring research to enable them to carry out investigations in this important field. The progress made by these institutions should be closely watched by the sponsoring research organisations and similar work carried out in other institutions should be properly co-ordinated.

2.7. *Research work by manufacturing concerns.*—The larger manufacturing concerns in the country have established special research laboratories for carrying out investigations on problems arising during the manufacture of their products. In recent years, some amount of original research has also been undertaken by them, which is being freely published. Firms in America and Europe maintain their own research laboratories, where a great deal of scientific investigation of the highest quality is being carried out. Although, this stage is still far off, there are indications that the research activities of manufacturing firms in India are likely to increase in the near future.

2.7.1. The volume of research work done in these bigger units is not keeping pace with the growing needs of the pharmaceutical industry. For example, there is no gainsaying the fact that some of the Indian firms which captured foreign markets during the War, lost them after the cessation of hostilities, because they could not achieve and maintain the same standards, and this was mainly because they could not improve the products to the same extent due to lack of research work.

2.7.2. In other countries, the majority of the new therapeutic agents which form, in each successive edition an increasing part of the B.P., B.P.C. or U.S.P., owe their development to research carried out by commercial firms. The present position in India is that the majority of the smaller pharmaceutical concerns are not even properly equipped with testing laboratories for either chemical or biological control. Only the large scale manufacturers are maintaining testing laboratories.

2.7.3. As a result of our investigations, we find that the larger concerns, barring a few exceptions, have laboratories equipped mostly for maintenance work and for dealing with *ad hoc* problems that arise in the normal working of the factories. Firms that are either branches of foreign concerns or are associated with foreign firms mostly depend on investigations carried out in foreign countries to provide them with their needs. They, however, maintain well-equipped testing laboratories. The average expenditure incurred on both research and testing activities comes to be about 4 per cent of the total sales. As a major portion of this expenditure is on testing, the amount spent on research is very nominal.

2.7.4. It has been argued that in the matter of development of research, the Indian pharmaceutical manufacturers have little opportunity of providing adequate finance for this purpose. The better established firms have to compete with a large number of small firms, which are licensed to manufacture pharmaceuticals and which put up cheap products regardless of their quality into the market. As the market still considers price before quality, the established firms have to compete with them and are, therefore, unable to include any provision for research within the price structure. We feel that if the activities of these small firms are better controlled by implementing the recommendations made by us in this respect in Chapter V, this difficulty will be removed to a great extent.

2.7.5. It should be made incumbent on the manufacturers to spend a certain percentage of their profits on original research. It was revealed during our enquiries that one concern was dividing its total profits into four parts and utilising one part for research and another for the welfare of the staff. They were running a premier research institute out of these funds, although their total profits were in no way excessive compared to other firms. This is very commendable indeed, and should be followed by other concerns. Some of the concerns are also financing research in University Laboratories and other research institutions. This seems to be a desirable feature and should be encouraged as it serves the interest of both parties. To the industrial concerns, it is more economical than having their own research laboratories and at the same time, it makes it possible for them to utilise the talent of the younger generation for their purpose. For the universities it helps them to expand their activities and provide students with opportunities of getting trained in this type of work. Research in such institutions should, as far as possible, be original.

2.7.6. It has been represented to the Committee that foreign firms holding patents in India in respect of drugs and medicines and which sell considerable quantities of such drugs in India and make good profits do not spend any portion of their profits for research within

this country. This has resulted in very few drugs being discovered within this country, and Indian scientists not getting sufficient chances for training in this field of research. The Committee feel that the foreign firms which have established factories in India and utilise the profits derived in India for research in their own countries should be asked to employ Indians in increasing numbers and give them training in research institutions run by them in their countries. They should also establish in India research laboratories as early as possible and spend a portion of profits on research in these laboratories or contribute financially towards development of research in the country.

2.7.7. Any contributions made by pharmaceutical firms for research to universities and other exclusive research institutions should be allowed a rebate of income-tax.

2.7.8. Among the research activities carried out by the firms, the following may be mentioned as most prominent:—

- (i) Manufacture of Sulpha drugs and related organic chemicals.
- (ii) The production of preparations of Rauwolfia and certain active principles of plant drugs.
- (iii) Medicaments related to the treatment of leprosy; and
- (iv) Improved preparations of liver extracts.

Certain firms have also undertaken investigations on the manufacture of antibiotics.

2.7.9. One important aspect of research, to which the industry has not paid much attention, is the pilot plant study of the manufacture of drugs that they have been investigating. A pilot plant study of the process, they intend to adopt, is necessary in order to arrive at an accurate estimate of the cost of production and obtain the necessary chemical and chemical engineering data for designing and setting up regular plant for the commercial production of the concerned drug. We find that many of them have switched over from laboratory investigations to semi-commercial production improvising equipment with a lot of glassware and rubber and reaction vessels only made of metal. Although such plants may be able to supply enough quantities of the drugs for putting them into the market, they will not help in any way to judge the economics of production of these drugs or supply the necessary data for putting up commercial plants. We, therefore, recommend that these firms should put up properly designed pilot plants with the help of standard chemical engineering firms or National Laboratories for investigating the economics of production of the method adopted and to collect sufficient chemical and chemical engineering data to be able to put up large scale plants for commercial production.

### **3. Scope for improvement and need for co-ordination on research work in India:**

3.1. If the major problems that are facing the industry are to be solved efficiently and quickly in order to enable the country to attain the same status, as other advanced countries in the manufacture of pharmaceuticals, the present research activities will have to be

greatly expanded and better co-ordination between the research work carried out by the different organisations brought about. Government's help in this direction is indispensable. They will have to subsidise largely the various research activities in the field of pharmaceuticals and drugs. Even in a country like America, where manufacturing concerns have vast resources, the Government contributes a major portion to research in medical and biological sciences when compared to research sponsored by private organisations. The Government's contribution in this country amounts to about \$100 million a year in the form of grants and Government Laboratory operations as against private research effort, which is of the order of \$50 million a year. The private research effort constitutes research sponsored by industrial concerns as well as Research Corporations, National Foundations etc. The efforts, at present, being made in India by Government and private organisations are very small compared to the efforts made in America and other advanced countries. The resources of private firms for financing research on an extensive scale are very little. Government should finance liberally research in pharmaceuticals and drugs in universities, medical colleges and other institutions and expand the activities in this field of the institutions directly under their control.

3.2. As developmental work in drugs involves team-work by specialists working in various fields like pharmacy, chemistry, microbiology, pharmacology etc., work of this nature should be entrusted to Government institutions like the Central Drug Research Institute, Lucknow, which are well-equipped with the various departments required for such work. These institutions should concentrate more on such type of work. Research work of a fundamental nature should be encouraged in university laboratories and other research laboratories, where there are no facilities for organisational efforts involving several research departments. The activities of commercial firms should also be encouraged on the same basis depending on the facilities they possess.

3.3 Broadly, we would indicate special emphasis on the following lines of research:—

- (i) Research on vegetable drugs of reputed value with a view to establish their therapeutic value on a scientific basis;
- (ii) Research for the discovery of new therapeutic agents for the treatment of diseases common in India such as malaria, tuberculosis, filariasis, leprosy, cancer, gastrointestinal disturbances like cholera, dysenteries and anaemias. New knowledge of drug action through enzyme systems should be utilised in making a new approach to the problems relating to the treatment of tuberculosis, leprosy and chronic amoebiasis; and
- (iii) Research for investigating new antibiotics from Indian sources. The modern period has been rightly called the antibiotic age and no country can afford to ignore this field of research.

3.3.1. A large number of new remedies, either antibiotics or synthetic drugs, have been introduced into medical practice in rapid succession. Adequate time has not been given to observe carefully their effects and it would appear that they reach the market too soon because of the keen competition among the large manufacturing firms. Certain drugs, which were originally considered to be safe, have on later investigations proved to be toxic. There is, therefore, great need for research institutions within the country to keep a careful watch about the effects of these drugs and make periodical reports. Unfortunately, at the present moment, the country is entirely dependent on foreign sources for any new information concerning their usage.

3.4. A panel of experts in different aspects of pharmaceutical science should be appointed to report periodically about the various drugs. Government should also release or publish these reports. Such organisations exist in foreign countries and give periodical reports about the existing drugs in their country.

3.4.1. It has already been mentioned earlier in this chapter that the utilisation of chemical research is handicapped for lack of adequate pharmacological work. After pharmacological and toxicological experiments, clinical trials have to be carried out. Representations have been made that a number of new compounds having possible therapeutical properties are being synthesised by many workers in India but adequate facilities for clinical and experimental trials of such compounds are not readily available. Arrangements have therefore to be made for undertaking such clinical trials. Army hospitals are particularly suitable for this purpose because the history of cases can be more fully recorded therein and followed up. These as well as other state hospitals, and hospitals attached to teaching institutions may be entrusted with this programme of investigation. The Panel of experts suggested above may be entrusted with this responsibility also.



## CHAPTER NO. VII

### DISTRIBUTION AND ADVERTISEMENT

#### (a) DISTRIBUTION

##### 1. General

1.1. Efficient and fair distribution policies play an important part in the furtherance of the development programmes of manufacturing concerns. The creation of a market for a product is dependent largely on the methods of distribution adopted. It is frequently made or lost especially in the counter of the retail pharmacist, which is the last stage of the product reaching the consumer.

##### 2. Methods adopted in other advanced countries:

2.1. In the U.K., both the wholesale and retail trade have been organised on an uniform basis. Manufacturers make all sales of pharmaceuticals through recognised wholesalers to the retail pharmacist, who, in turn, supply them to the consumers. Retail pharmacists usually nominate the wholesalers, through whom they wish to draw their supplies. In case, no wholesaler is nominated, the manufacturers make supplies through the nearest wholesaler and not direct to the retail pharmacist. Even in the emergencies, when stores are delivered by the manufacturers direct to the retail pharmacist, the bills are presented for payment through the wholesalers. In England, the retail pharmacist is usually allowed a discount of 33½ per cent of the listed retail price and the wholesaler a discount of 12½ per cent on the price at which the goods are invoiced to the retailers. An organisation styled the Proprietary Articles Trade Association (P.A.T.A.) composed of a body elected from manufacturers, wholesalers and retailers, control the trade. This association combats price-cutting and ensures distributors a fair remuneration for their services. It has stabilised the trade in drugs and medicines, eliminating all malpractices that result from price-cutting to an extent that any amount of legislation could not have carried out.

2.2. In U.S.A., the system of distribution is slightly different. A manufacturer reaches the physician and the consumer through three major outlets, the wholesale druggist, and physician's supply house and the hospital pharmacist. Most of the firms, however, prefer supplying through regular trade channels, although some supply direct to the physician and the hospitals, their prices to the hospitals being the same as to the retailers. The wholesale druggists are of four different categories: the full line service wholesaler, the special service distributor, the full line mutual wholesaler and the short line jobber. The wholesale and retail trade are regulated by the Fair Trade Regulations enforced both by the Federal as well as the State authorities. A discount to the retail pharmacist amounting to 40 per cent of the consumer price, and a discount to the wholesaler, amounting to 16.2/3 per cent. of the price to the retailer, are allowed.

2.3. In these countries, the educational background of the retail pharmacist, and the training acquired by him to meet the present day medical needs, are also responsible for the ethics of the profession being followed and the nature of their dealings maintained at a high level. He is not only of assistance to the pharmaceutical manufacturer in promoting the sale of his preparations, but also to the physician in the choice of his pharmaceutical speciality. The history of the growth of pharmacy in the U.K. and U.S.A. shows, that the distribution trade of pharmaceuticals has also passed through the stage that exists, at present, in this country. At one time in these countries, the sale of medicines by general stores was as common as in India. The dispensing and sale of medicines were undertaken by physicians and the so-called pharmacists, that existed, were ignorant of the nature of preparations, that they dispensed and the materia medica in general. Pharmacy was mostly considered to be a simple trade and was quite often changed for another, if the expected profit did not materialise. It was founded usually by physicians and was sold later to their clerks. Drug stores most often changed to general stores or to wholesale business. These conditions gradually changed and the present day pharmacy, which specialises in the sale of medicinal preparations was evolved. A step, that greatly helped in the evolution of the present day pharmacy, was the minimum educational requirements that were prescribed by Government for running the stores and the restriction in their number to the proportion needed to handle the demand for pharmaceutical service. With this scientific training and economic security, the pharmacists were able to concentrate profitably on their profession and serve the society as the responsible distributors for medicinal goods. The standardisation of pharmaceutical products, that came later on, did not prove a challenge to them but helped them to fulfil better their role in society and earn the trust of the public. A number of professional and trade associations were formed, which took upon themselves the regulation of different branches of the trade and the industry. For instance, in the U.K. the Pharmaceutical Society is responsible for the education, examination, registration and discipline of pharmacists. The Association of British Pharmaceutical Industry established in 1949, as a wholesale drug trade Association, concerns itself with problems relating to manufacture as well as whole-sale activity. The P.A.T.A., formed in 1896 deals with the wholesale and retail trade. In the U.S.A. organisations like the American Pharmaceutical Association and the American Manufacturers' Association carry out similar functions. The Pharmaceutical Industry in these countries has also profited by the improvement in the education and status of the retail pharmacist. The retail pharmacies provide a continuous flow of trained men to the pharmaceutical industry. In some instances, retail pharmacies have themselves ultimately developed into large pharmaceutical manufacturing concerns. They form the nucleus of the pharmaceutical industry and are, therefore, fostered by the industry to develop and work on healthy lines.

2.4. Many other countries have followed the example of U.K. and U.S.A. and have taken steps to create an atmosphere for a healthy trade in pharmaceuticals to develop. In Syria, the law prohibits the installation of a surgery on the premises of a pharmacy or as an

annex to a pharmacy. It prohibits the supply of drugs by the physician to patients with the exception of those distributed as free samples or in cases of emergency, and it makes it obligatory for every physician to write prescriptions legibly and to sign them. It prohibits a medical practitioner to own a pharmacy and carry on a retail sale of medicinal or chemical products. It is obligatory to hold a licence to engage in trade of drugs and chemical products; and every drug store must have a proprietor, partner or employ a person, who is a pharmacist authorised as such to practice in Syria. Authorisation is granted, in special cases, to open shops for the retail of simple drugs only in localities, where there is no pharmacy.

2.4.1. In Germany, it is obligatory on every pharmacist to possess a sufficient selection and stock of pharmaceutical products and to supply them to customers, subject to the regulations for the supply of such products. Permits to engage in trade in medicaments is granted to medical practitioners only in localities, where there is no local pharmacy. Even in such places, the permission for grant of a permit to engage in medicaments to medical practitioners is given only to those, who successfully pass an examination in pharmacy referred to in the Pharmacy Examination Regulations. Admission to this examination is limited to persons, who have had six consecutive months' experience in a public pharmacy or a hospital pharmacy. Clinical establishments and nursing homes desiring to establish a pharmacy must prove a compelling need for the same and, even then, it must be under the personal supervision of a pharmacist, who satisfies the requirements for carrying on of a pharmacy under the German Regulations.

2.4.2. In Monaco, the carrying on of a dispensing pharmacy is stated to be incompatible with the exercise of any other profession including that of a physician, general surgeon or midwife and no pharmacy can sell secret remedies. Medicines and products, whose sale is limited to pharmacists, can be sold to the public only at prices laid down in the scale of pharmaceutical charges, recommended by the College of Pharmacists and approved by order of the Minister of State.

2.4.3. In France, it is reserved to the pharmacists, amongst other things, to sell by wholesale or by retail and deliver to the public all medicines intended for the use of human beings, that is to say, every drug, substance or composition presented as possessing curative or preventive properties in respect of human beings, ready packed or labelled with a view to sell for medicinal use and also the sale of medicinal herbs described in the French Pharmaceutical Codex. All pharmacists should be holders of the diploma of pharmacy given by the Government, and should be registered at the National Union of Pharmacists. Hospitals, Asylums, Clinics, Sanitary health homes, Dispensaries and in general all public or private institutions, where the sick are treated can be owners of a pharmacy on condition, that it should be managed by a pharmacist, under whose supervision and responsibility medicines should be distributed. Medical practitioners, who are established in centres, where there is no pharmacist having a pharmacy opened to the public, can be authorised by the Prefect on the advice of the Regional

401

Director of Health to have with them a stock of medicines and to issue to persons, who are under their treatment, medicines which figure on a list prepared by the Minister of Public Health on the advice of Superior Council of the Union of Physicians and of the National Council of the Union of Pharmacists. This is, however, liable to be revoked at any time as soon as a pharmacy is opened to the public in the centre. Medicines and products should be sold to the public only at prices fixed by the National Pharmaceutical Tariff. This Tariff is proposed by the Federation of Syndicate of Pharmacists and ratified by a Ministerial decree from the Ministry of Finance, Public Health and Population in accordance with a set procedure.

### **3. Position in India and Steps necessary for its improvement.**

3.1. In India, there is no uniform system or principle of distribution being followed or proper control on the retail trade. The importers and manufacturers supply the pharmaceuticals direct to the wholesalers, retailers and physicians as the case may be from the ports and factories. Some manufacturers distribute their products through their branch offices situated in big towns. Retail traders are also appointed as distributors on a contract basis, the contract being that they should buy a fixed amount during a year, for which they are given an extra discount. The discounts allowed to the trade vary over wide limits from  $6\frac{1}{2}$  per cent to 25 per cent and additional discount allowed to those who work on contract basis vary from 5 to 10 per cent. This diversity in the discounts allowed and the low margin of profit that it generally yields are not conducive to an efficient system of distribution. Numerous stores deal in drugs as a result of which price-cutting on a colossal scale is practised. All business is transacted with reference to price alone and not with reference to quality. A competition in price, instead of quality, has been ruinous to all—the industry, the trade and the consumers and has resulted in the demoralisation of the trade. Adulteration, trickery, short-weight and even sale of spurious drugs are being resorted to in order to exist with the low margin of profit, that this price-cutting allows them to make.

3.2. Distribution in India, today, is passing through the same phase, which existed in other countries years ago and it is high time that something is done to stabilise the trade and lead it into proper channels. The prime factor to be looked into is price-cutting, which is not only injurious to the goodwill and business of the manufacturer and distributor, but also to the general public. In the U.K., under the aegis of the P.A.T.A. as one of the national institution, the maintenance of minimum selling prices has become a success. In the U.S.A. also, the maintenance of a minimum selling price under the Fair Trade Laws has come to be established as a public policy. A recent decision by the U.S. Supreme Court has passed a constitutional authority to the Fair Trade Laws in the legal battle that ensued when a super market sold various drugs produced by Eli Lilly & Co. below the fair trade prices fixed by them. From now onwards, the manufacturers and wholesalers can fix the retail price of their branded and trade marked goods in 45 out of 48 States. The principle of maintaining retail prices, which have been fixed by the manufacturers is adopted in about twenty countries. The essential aim of the

retail price maintenance is to assist an even and economic flow of goods between the producer and the consumer and this system ensures protection of the trade marks, which provide the consumers with a guarantee of quality.

3.3. Fixation of a fair price ensures a fair margin of profit to the channels of distribution at all times and the practice of inflating prices during periods of shortage, which is now being resorted to becomes impossible. An honest effort must be made to arrive at a fair and equitable selling price. This price must be high enough to provide minimum margins of profit, which should be fixed at both wholesale and retail levels after critical and unbiased study of handling costs. Most of the manufacturers are now anxious to establish their selling prices to the consumers as low as possible only by reducing the profit margins to the wholesalers and retailers. They, very often, function as wholesalers and retailers themselves. The wholesaler cannot operate efficiently as retailer, nor can the retailer operate as a wholesaler. Neither can a manufacturer do both. It is, therefore, imperative that the different branches of the trade should be distinct and allowed to develop separately on healthy lines by ensuring a sufficient margin of profit at all levels. The producer cannot, as a practical procedure set up different minimum prices in different areas, or for different stores in a given area. He can only proportionately set up minimum selling prices for average volume of sales. The competition between the manufacturers must be the factor to set fair prices and it is recognised that no trader, wholesaler or retailer has authority or the right to name the price at which it shall be sold to the consumer.

3.3.1. The Fair Trading Laws of Florida have a Preamble, which, in no uncertain terms, declares price cutting to be a predatory, unfair and discriminatory practice and establishes the fact that the maintenance of minimum resale prices of commodities is in the interests of and promotes the general welfare of the State of Florida. Drug and drug products are invariably the one commodity common in all fair trading laws all over the world.

3.4. The first and foremost thing to prevent this price-cutting and the malpractices that result from it, is to restrict the sale of drugs and medicines only through qualified pharmacists. The present practice of selling drugs and medicines in grocer's shops, restaurants and general merchants in cities and large towns due to the very low fee fixed for licensing in forms 20 and 21 under the Drugs Rules and for the lack of enforcement of minimum standards of premises, personnel and equipment should be stopped. An increase in the licensing fee and enforcement of minimum standards as recommended in Chapter V of this Report will help in achieving this.

3.5. Fixation of a fair trade price and the abolition of price-cutting as the only means of competition among retail drug stores is essential. The system of making all supplies only through wholesalers as practised in the U.K. is not practicable in this country because of its vastness, nor are there specialised channels like the physician supply houses, etc. as existing in the U.S.A. It is, therefore, necessary that in this country a system should be evolved which, while protecting the existing channels of distribution, would

help in placing them in a sound position. The existing system of distribution should, therefore, be organised in the following manner:—

- (a) Normally, no manufacturer should be allowed to set up in the trade as a distributor; but should utilise the existing channels. The established traders should be encouraged to act as distributors.
- (b) No trader should be allowed to trade both as a wholesaler and retailer in the same premises.
- (c) The wholesale establishments should be further divided into:—
  - (i) Regional distributors handling the products of a limited number of manufacturers and/or importers; and
  - (ii) General wholesalers dealing in all types of drugs and medicines from all manufacturers and importers.
- (d) Dispensing of drugs should ordinarily be done by Pharmacists. A person should be allowed to enrol either as pharmacist or as a medical practitioner but not both. Medical practitioners may, however, be allowed to dispense drugs to their own patients. The medical practitioners should, as far as possible, employ qualified persons to do the dispensing work. It should be considered necessary for them to maintain minimum equipment and requisite storage arrangements and adequate maintenance of proper records on the lines of those provided under the Drugs Rules.

Each of these different branches of trade are distinct and separate and have a definite part to play. They should be ensured of a proper return to assist them to develop on healthy lines; and the tendency among manufacturers and importers to disrupt these normal trade channels and take over their duties, should be discouraged.

3.6. To prevent any undue inflation of the price, a system of fair trade prices should be established and the existing price-cutting which leads to many malpractices including the sale of spurious and adulterated drugs should be stopped. The consumers' price of all drugs and medicines should be fixed by an organisation representing the Government and Trade. A catalogue showing such Consumers' prices should be published and made available for inspection at every Chemist's shop. In the present state of the profession, anything that has not got a governmental backing, is bound to fail. While we do not believe in any sort of control over the trade, the present state of the pharmaceutical trade demands some control over the price-cutting now in existence, which leads to a lot of malpractices including the sale of spurious and adulterated drugs to the public.

3.6.1. In order to give the public a sense of security as also a stability in the prices for drugs, it is essential that this price-cutting should be checked and the trader made to sell at the prices so fixed to the consumer, and any deviation should entail the cancellation of the licence.

3.7. Considering the economic level of the consumer in this country, the discount to the trade should be fixed at a reasonable figure which we consider as 25 per cent. off the consumers' price. This discount of 25 per cent. must be free of all costs of transport and must represent the margin of profit ex-sellers' premises. This margin of profit was allowed to the retail trade during the war in the Drug Price Control Schedules. The discount allowed in other countries varies from 40 per cent. off the consumers' price in U.S.A., 33.1/3 per cent. in U.K. and 25 per cent. in some of the Middle-European countries, and Germany.

3.7.1. The territorial distributor should have a discount of 10 per cent. of the price at which goods are sold to the trade *viz.*, the retailer or wholesaler with an extra 1½ to 2 per cent. to cover packing etc.

3.7.2. In order to keep the present wholesaler in the trade, it should be the practice that the importer or manufacturer should sell only in certain specified lots, and when a trader wants a quantity less than this specified lot, he should obtain it from the general wholesaler.

3.7.3. The general wholesaler should sell at a price which gives him a profit of 10 per cent. and pass on the balance to the retailer.

3.7.4. The present practice of certain manufacturers and importers making supplies direct to the hospitals in consumer packs at prices lower by as much as 15 per cent. than the prices to the trade, has got to be stopped. Such supplies may have a way of finding themselves into the open market and disrupt the normal trade. Where such prices are offered to the hospitals it must be for special hospital packs only and when supplies are made in the ordinary packs the prices to the hospital should not be lower than those to the trade. As far as possible, even supplies to the hospitals should be through recognised trade channels.

3.8. The position with regard to the movement of drugs is not satisfactory at present. Considerable delays occur arising out of a shortage of wagons. A high priority should be given to the transport of pharmaceutical products, which are vital for the well-being of the public. Consignments of medicines should be provided with special 'rush labels' so that even small packages could be moved at a faster rate.

3.9. Under the Drugs Act and the Rules thereunder, biologicals and other heat sensitive drugs are to be kept in cold storage, so that they may not lose their potency. But during transit from one part of the country to other, no cold storage facilities have been provided on the Railways with the result that they are likely to deteriorate during transit and the consumer does not get the requisite response after their use. Hence it is necessary that the Railway authorities should provide cold storage facilities both in the wagons and the godowns for storing heat sensitive medicinal products.

3.10. At present, medicinal preparations and luxury articles are classified under the same heading for the levy of tariff rates, which are high. It cannot be denied that medicines and medicinal preparations are more important and are in greater demand than luxury articles. These rates should be reduced to conform to the lower parcel rates, which will help in reducing their price to the consumer.

## (b) ADVERTISEMENT:

## 1. General:

1.1. Advertising of drugs and medicines form part of an efficient distributing system. The aim of every pharmaceutical manufacturer is to establish his products as a successful seller, and advertising plays a very important role in such establishment. As such controls on media, and methods of advertising any product should be undertaken with great care, considering that advertising is the essential psychological factor for the popularity and sale, on which the future of the manufacturer depends.

1.2. The advertising of pharmaceuticals depends on whether the product is an "Ethical" product (whose sales depend on its being prescribed by the medical practitioners) or a "Proprietary remedy" whose success depends on the creation of a market directly with the public without the intermediary of the medical practitioner. It is the latter class of goods that help "self medication" and ought to be controlled by legislative measures. The ethical goods sold through the medical profession are advertised as follows:—

- (i) by medical representatives, who call periodically on medical practitioners and leave with them clinical reports, literature and samples of the products for trial;
- (ii) by direct mailing service giving latest trial reports and discussions as to the composition, therapeutic dosages etc.; and
- (iii) through advertisements in Scientific and Technical journals.

## 2. Medical Representative:

2.1. Such advertising for the promotion of ethical products is essential and the medical representative or the 'detail man' as he is known in foreign countries, plays a very important role. It is a pity that Indian manufacturers do not pay sufficient attention to this side of their advertising at present. It is necessary that these 'detail men' should be properly trained in the factory before they go on their rounds and are made conversant with the nature of the product, their chemical composition and the indications and dosage, and the controls they undergo in their manufacture. A good 'detail man' should be a properly qualified person at least with a fair knowledge of pharmaceutical chemistry irrespective of his being a medical man or not. But the present set up of 'detail men' touring the country on behalf of Indian manufacturers are of very poor quality. As long as these ill-trained 'detail men' are not replaced, we do not see any hope of the Indian manufacturer ever foregoing ahead in his market and be a serious competitor to any foreign manufactured product. More attention has to be paid by them to this angle of advertising ethical medical products than to direct mail or advertisements in the medical journals of the country. There are enough qualified men for these jobs in India and a larger number of them are in the employ of foreign firms than in Indian firms due to their being able to get better remuneration. It would be a great advantage if the Indian manufacturers get together and arrive at a reasonable minimum salary and



amenities for their 'detail men' in addition to benefits of provident fund, sickness allowance to them and their families. The Indian firms will then be able to build up an efficient and experienced field force and will not change them very often as is the case now. There is no fixed method that could be adopted for the successful marketing of any product as it depends on various factors, a few of them being:—

- (i) Is the product entirely new and possessed of dramatic effects that will draw wide attention in the medical journals and of medical men in their meetings or is it of minor and prosaic advantage?
- (ii) Is it indicated in the treatment of common widespread conditions or has it only a limited use?
- (iii) Is it a product that could be used by general practitioners or is it confined to certain specialists only?
- (iv) Is the product a general or seasonable one?
- (v) Is the product an exclusive formula covered by patent rights conferring exclusivity for a period or a prestige item to reflect credit upon the name and other products of the firm?
- (vi) Will the product be self administered by the patient or is it a prescription item to be administered by or only on the prescription of a medical practitioner?

2.2. By and large the problem is not one that could be solved by a rule of thumb and entirely depends on the finances available. Information gathered by the Committee from various firms gives varying figures from 5 per cent. to 40 per cent. on straight advertising and 20 per cent. to 50 per cent. on detail men; and in any case, no hard and fast rule could be stipulated. This is a detail to be worked out by every manufacturer according to the product and the Committee could only state that advertising by detail men and in medical journals followed by direct mailing is the best; and good results are likely to be obtained by a judicious combination of all the three. Failure to advertise so as to make the product popular among the medical practitioners will certainly lead to a dwindling of the sales and eventual withdrawal of the product. Any result obtained by direct mailing is often vitiated by the manufacturers not arranging for supplies of the drugs to be available with the local chemists. It should be possible for them to arrange at least for small supplies of any new product, about which the literature is being mailed to the medical practitioners of a town, with retail chemists in the area, so that any prescription for the drug is met promptly and the patient has not to go back to his physician for an available substitute as the prescribed drug is not available. Frequent occurrences like this create a bad impression with the prescribing physician which does no good to the manufacturers.

### 3. Methods adopted in advanced countries:

3.1. In the U.K., in spite of provisions in the 1938 Act regarding labelling and advertisements, in practice, action is seldom taken even though extravagant claims sometimes appear in advertisements for

proprietary medicines sold direct to the public. The probable explanation for this is to be found in the enforcement provisions of the Act.

3.2. Enforcement is the responsibility of the so-called Food and Drugs Authority, which in most cases, is the Local County Council or Borough Council. Generally, members of the Local Authority responsible for spending local funds are reluctant to take action against a national advertiser at the expense of local funds. While dealing with advertisements of drugs, reference must be made to the highly effective and realistic treatment which such advertising receives under the "British Code of Standards" in relation to the advertising of medicines and treatments. This Code is drawn by an Advisory Committee of Newspaper Proprietors. National Newspapers do not accept advertisements, which fail to conform to the Code.

3.3. In addition, there is an organisation known as the 'Chemists Federation', which has effected a very significant improvement in the labelling by the manufactures, wholesalers and retailers in business. Before a product can be introduced to the public, the formula is considered by a Committee on Standards and the label critically examined to ensure that no extravagant claims are made. There is no organised control on the advertising, whether in scientific journals, newspapers or in direct mail propaganda of ethical prescription specialities.

3.4. In Canada, the Food and Drugs Act controls advertising also. Schedule 'A' of this Act lists disease conditions, for which no drug may be recommended or sold to the public. This list is revised from time to time and includes cancer, diabetes, tuberculosis, venereal diseases and disorders of the menstrual flow. The purpose of this Schedule is to obviate the necessity of proving that the claims are false and more effectively to discourage exploitation of the public through the sale of articles for treatment of diseases that cannot be treated safely and effectively through self-medication. The Canadian Act has limited value in dealing with the problems that are becoming more common today in India. Most of the advertisements in India to the lay public are in terms of symptoms rather than of specific diseases. To day, there are a few examples of labelling in which specific diseases are mentioned. The usual 'promotional material' features symptoms, which may be caused by one or several diseases specifically named in the Canadian Schedule. A similar problem exists in Canada which limits specific action under this schedule e.g., Obesity treatment sold as a dietary balance, would hardly offend schedule A's prohibition of sale of a drug for the treatment of obesity. Such claims might, however, offend the provisions against false, exaggerated and misleading advertisement. The Canadian Act contains a provision, whereby an advertisement for foods and drugs is made subject to it. Section 32-A provides that it is an offence to advertise the food or a drug in a manner, which is misleading or likely to create erroneous impressions regarding its value, composition or safety.

3.4.1. Section 3 which is the regulation making section authorises regulations respecting false, exaggerated and misleading claims for food and drugs, and this authority is not limited to labels alone.

3.4.2. The control of new drugs is not provided in the Canadian Act other than the general provision in the Act to define the conditions of sale of any drug in the interest of, and for the protection of, public health. Under this authority, new drugs are dealt with on an *ad hoc* basis. This may involve prescription control as was done in the case of the drug "antabuse", or, in the case of special label warnings, as has been done for vitamin preparations, or by making them subject to special regulatory control.

3.4.3. While this has generally proved to be adequate in the past, it is now not considered as a satisfactory method of handling new preparations as is provided by the special legislation in the American Act; and special provisions are under discussion with the trade representatives. The wide power, however, which is contained in the Canadian Act to deal with the subject by regulations, will permit new drugs to be so dealt with and will not involve any amendment to the Act.

#### 4. Advertisements of unethical products:

4.1. The problem of the unethical product, which is invariably a proprietary remedy with undisclosed formula is the one that should be attended to immediately. The following statement from the Council on Pharmacy and Chemistry of the American Medical Association expresses the attitude of the medical profession in U.S.A. on this point:

"Indiscriminate self medication by the public involved grave dangers, such as misdirected and inadequate treatment, failure to recognise serious disease until it is too late for effective treatment, and the spread of infectious diseases when hidden from a responsible physician. All these are involved in the advertising of drugs to the public with the further dangers of suggesting by description of symptoms to the minds of the people that they are suffering from diseases described, the dangers of the unconscious and innocent formation of a drug habit and the dangers of starting allergic reactions."

A majority of the medical profession will concur with this. It must be conceded that the dangers specified above do not apply with equal force to all products advertised directly to the public, and direct advertising could safely be confined to disinfectants, insecticides, germicides, antiseptics promoted for prophylactic use on superficial cuts and abrasions of the skin, mild laxatives, antacids, relatively safe analgesics, cough remedies and general restorative tonics.

4.2. Unfortunately, such advertising does not end there in this country. One has only to open the news papers to be confronted with such headlines as "Asthma germs killed in 30 seconds" "No matter how severe or long standing, diabetes can be completely eliminated from your system by a new scientific new theory non-injection treatment discovery available in tablet form" and the tour programmes of practitioners of indigenous system of medicine, who promise to give effective relief in cases of heart diseases, nervous debility, digestive disorders, blood poisoning, insanity, diabetes, hysteria, piles and Asthma by their famous 'Basmams' made out of pearls, gold and

copper. The newspapers in Indian languages are the happy hunting ground for manufacturers of such drugs and the following translation of an advertisement appearing in a reputed Tamil Weekly will illustrate the point:

"Pill Regd. CDL—Your monthly course restored immediately whatever the cause of its stoppage and however long it had ceased. Innumerable testimonials for this wonder medicine. Do not be taken in by fraudulent imitations. Guaranteed cure."

How CDL numbers are given to these sorts of remedies is a matter to be investigated thoroughly. Such exploitation of the credulous public should be put an end to.

4.3. The words "patent and proprietary medicines" were applied more to secret proprietary medicines or nostrums. It was clear that these preparations were becoming increasingly popular and their sales were very much on the increase. Among the causes for their acknowledged popularity, the Chopra Committee noted the following:—

"The pride of place must be accorded to ingenious propaganda clever and attractive dissemination of their supposed virtues and wide and alluring advertisements. The credulity and gullibility of the masses, especially when 'certain cures' are assured in utterly hopeless cases, can well be imagined. Perusal of the advertisements of 'cures' produces a great effect on patients who have tried treatment by medical men without success. Such patients resort to any and every drug that comes in their way. In an infinitesimal small number of cases spontaneous cures are also effected. Widest publicity is given to these and the preparations become invested with miraculous virtues. The reassurance of cure, the force of argument advanced to guarantee it and the certificates of persons said to have been cured which are all set out in advertisements make a deep impression, especially on those with weak nerves. The love of mystery and secrecy inherent in human nature, the natural disinclination and shyness to disclose details of one's illness especially those involving moral turpitude, the peculiar treatment of the people who, high and low, rich and poor, demand 'something in a bottle' for the treatment of every ailment and the poverty of the people who cannot afford to pay the doctor's bills or the high prices current for dispensed medicines, have all been enlarged upon as tending to self-diagnosis and self-medication by patent and proprietary medicines. The fact that a number of these drugs have some value and are efficacious on account of their excellent combination and the circumstances that the medical practitioners frequently prescribe them are also urged in their support."

"Notwithstanding the usefulness of some of the patent and proprietary medicines, an overwhelming number of witnesses deprecate the increasing sale of proprietary

medicines, particularly those with secret formula. Not a few consider such drugs positively harmful and believe that they are a 'serious and increasing menace which is frequently fraudulent'."

"The most perfunctory study of the advertisements and pamphlets issued in connection with patent and proprietary medicines will disclose 'fraudulent practices of a most abominable character'. Extravagant claims, grossly in excess of those justified by the ingredients, are made without the slightest regard for truth. The books entitled 'Secret Remedies: what they cost and what they contain' published by the British Medical Association have exposed the fraud ruthlessly. The results of the analysis of many medicines showed that they often contained cheap substances which had no medicinal effect. The cost of the ingredients bore no relation to the price actually charged. That they are unnecessary and act as a drain on the national purse is stressed."

The misery, 'breakdown in health and mortality that might follow the use of some of the patent and proprietary medicines cannot possibly be over-estimated."

The production of such medicines prejudices the legitimate use of approved remedies and leads to what may be called 'proprietary prescribing'. The practitioner is not left unaffected by the propaganda in furtherance of such medicines. Its action on him is in the nature of a compelling suggestion."

4.3.1. It is fair to point out that the Chopra Committee did not condemn all patent and proprietary medicines. In particular, they noted that the position of proprietary medicines with disclosed formula was ethically sound, as these were manufactured by firms of repute and their definite composition made it possible for the conscientious practitioner to judge their value for himself.

4.3.2. The Chopra Committee stated that there were no laws in India to check or regulate the import, manufacture and sale of patent and proprietary medicines, except in so far as they contain dangerous drugs or poisons, and they emphatically recommended a strict measure of control.

4.4. Whilst stringent labelling provisions are laid down in the Drugs Rules, these unfortunately do not apply to advertisements in the lay-press or medical journals or to literature supplied to Doctors. For instance, some of the literature circulated to the medical profession lays stress only on their patented and proprietary names without any mention of the scientific or official name of the drug. This is a serious lacuna which needs to be rectified if the blatant and even false claims often made by unscrupulous manufacturers are to be stopped.

4.4.1. Recently, a very comprehensive Advertisement Bill was passed by the Council of States and discussed and adopted by the House of the People. This Act will give adequate powers to the Authorities to deal with false and unjustifiable claims in advertisements.

4.4.2. The newspapers and especially publishers of journals in Indian languages in this country should themselves set up a code of advertising and, if necessary, the State should step in to put an end to suggestive advertisements which exploit the credulous public.

4.4.3. The manufacturers of medicines under the non-allopathic systems like Ayurvedic, Unani and Homeopathy on which there is no control at present, are the worst offenders.



सत्यमेव जयते

## CHAPTER VIII

### MEDICAL PROFESSION AND THE PHARMACEUTICAL INDUSTRY

#### 1. General:

1.1. During the earlier part of the Century, the medical profession in India had to depend solely on imports of drugs, medical preparations, injectibles etc., from foreign countries. During the period of the First World War, a small impetus was given to the pharmaceutical industry during which time 20 to 25 per cent. of Galenicals, and other drugs, used by the medical profession, were manufactured in the country. Immediately after the War, there appears to have been a set back and the industry was not of much assistance to the profession. Between the two Wars, attempts were made in various parts of the country to reorganise the industry and supply the demand of the various drugs required by the medical profession in India. Very many people were encouraged to take up this industry, especially during the time of the Second World War, when supplies from foreign countries were practically cut off. In addition to the demands made by the medical profession on the civil side, the indigenous manufacturers had to supply the demands of the Defence Forces (Army, Navy and Air Force) which resulted in a great fillip to the industry. During this period, practically the whole of the medical profession was forced to use the available drugs, which were mostly manufactured in India. Immediately after the cessation of hostilities, there was a set back in the progress of the industry due to various causes, the most important of which was non-maintenance of standards.

#### 2. Supply of drugs and pharmaceuticals etc., to Medical Profession

2.1. It is gratifying to note that there is now a well-organised net work of distribution of medical supplies. Little difficulty is now being experienced in obtaining the necessary drugs in any part of India, especially in areas, where the medical men trained in modern medical science are practising. Even the villages are now being gradually supplied with modern drugs due to the greater influx of people, partly trained in modern medicine. It is hoped that with greater attention being paid to the rural welfare, the availability of many of the necessary drugs in the remoter parts of the rural areas will also be greatly improved.

2.2. There is a general clamour that in order to secure benefit to the public, an early decision on application for permission to import must be taken. Delay leads to disappointment in many cases. The Expert Body proposed in Chapter IV and the Development Council for pharmaceuticals and drugs when formed, should pool their knowledge and resources together in determining the

essentiality of a product and the necessity for its import. In doing so, they should work more or less on the lines of the American Medical Association.

2.3. The medical profession has expressed difficulties in obtaining laboratory reagents and stains etc., promptly owing to import difficulties. According to them, the same difficulty has also arisen with regard to surgical dressings, appliances and insecticides. This needs investigation.

2.4. As things stand at present, the Government Medical Stores, wherever they are in existence, do not cater to the needs of the general medical practitioners. Certain essential articles such as antivenine sera manufactured in Government institutions like the Haffkine Institute are not made available to the general practitioner. It is suggested that the preparations and articles in the Medical Stores and other government institutions must be made available to the general practitioners who should be in a position to obtain them at very short notice.

### **3. Questionnaire for the Medical Profession:**

3.1. For the purposes of ascertaining the views of the medical profession, a detailed questionnaire (Appendix No. 4B) was issued to medical colleges, State Public Health Authorities and medical associations. A majority of them have responded and given their views. A list of medical educationists and Public Health Authorities, who replied, is given in Appendix No. 13. It is gratifying to note that the replies received have been fully representative. There has been a remarkable agreement in the opinions expressed by the medical profession, medical educationists, private practitioners, and Government medical and health officers.

3.2. As a result of scrutiny of the replies, it is noticed that the majority of practitioners and hospitals use about 60 to 80 per cent. of drugs of foreign manufacture, and 20 to 40 per cent. of indigenous manufacture. The low percentage of indigenous manufactured products is possibly due to the essential drugs like antibiotics and chemotherapeutic drugs not being produced in the country, and the want of confidence in indigenous preparations. The Indian manufacturers have to make better attempts to win the confidence of the medical practitioners as well as the general public for their preparations. Complaints have been made that the Indian manufactured drugs are not upto standard and that very many sub-standard preparations have come into the market during recent years. It is increasingly felt that with greater attention on the part of the manufacturers and the Government, they could maintain the required standards, and at the same time, with stricter supervision and control, check the sale of substandard and spurious drugs.

### **4. Co-operation of the Medical Profession:**

4.1. Sufficient co-operation from the medical profession and the public is necessary for larger utilisation of indigenous products. The medical profession should realise that the pharmaceutical industry is a vital industry, which plays an important part in maintaining the health of the State and that every product manufactured



should be utilised to the fullest extent by the medical profession, provided the article comes upto the required standard, both in its efficacy and purity. To create the necessary confidence, it should be the endeavour of the indigenous drug industry to establish their own testing laboratories so that their raw materials, intermediates and finished products could be tested and a control maintained on the different stages of manufacture. It may also be necessary, as already suggested earlier by the Committee, to have more independent testing and analytical laboratories set up in the country jointly by the industry and the medical profession for certifying the products.

4.2. To a certain extent, the unwillingness of the medical profession in India to use indigenous drugs is also due to want of sufficient publicity. The science of advertising has not yet been adequately mastered by the Indian manufacturers. Lack of funds may be an important factor but methods should be found to combat this.

4.2.1. With regard to advertisements, majority in the profession are in favour of continuance of the receipt of a fair amount of literature from the industry. They at the same time deprecate too frequent receipts. It cannot be denied that abstracts and copies of articles from reputed journals in support of the drugs are useful in educating the profession, especially the members, who are in the remoter areas, where recognised medical journals may be difficult to obtain. The presentation of the literature varies from firm to firm. There is no denying the fact that, when the get-up looks neat and attractive, the tendency to read the matter contained therein is greater than, when it is of a flimsy type. An elegant presentation is appreciated while elaborate multi-coloured engravures should be deprecated, as they increase the cost of drug, which the consumer has to bear ultimately.

4.3. Clinical investigations on new products are absolutely essential before being used safely by the medical profession. It is, therefore, necessary that pharmaceutical manufacturers should have their own hospitals or endow some beds in the hospitals in the vicinity of their factories where their products can be clinically tested.

## **5. Use of compounded preparations in modern medical practice:**

5.1. There is an overwhelming feeling that the country is flooded by a large number of superfluous preparations mostly from foreign countries, thus straining our foreign exchange position. With the advent of antibiotics and Chemotherapeutic agents, the medical profession is rapidly losing the art of prescription writing and the pharmacists do not have the same amount of compounding to do as before. Very many firms take up prescription-writing, tableting or ampouling or using in a mixture form, with or without alcohol to be of ready use both to the profession and the public. This must be checked, even if it is sometimes inconvenient to the doctor.

5.1.1. This tendency has to a very large extent been responsible for a set back in the teaching institutions. The professors and other medical men engaged in teaching often teach the students patent and trade names and the number of tablets to be taken rather than

give them the scientific name and the dosage of ingredients on scientific basis, with the result that very soon the scientific aspect of the drug is completely forgotten and only its proprietary and patent name remembered by the student and the teacher. If this state of affairs is allowed to continue, in addition to its being costlier Doctor's pharmacies would be reduced to the position of mere selling agents for prepared drugs.

5.2. The use of patent and proprietary drugs has assumed such enormous proportions during the last few years that the treatment of diseases has become very much costlier than it used to be previously. In addition, it has also led to self-medication which is dangerous and needs to be condemned. Some of the practitioners are of the opinion that a provision for a few household remedies such as balms, antacids, mild laxatives etc., may be necessary. Symptomatic treatment is sometimes necessary but every attempt must be made for arriving at a diagnosis in practically all cases. It is a moot point whether symptoms should be promptly treated except in minor and trivial complaints. The following extracts taken from the "Journal of American Medical Association, dated 22nd August 1953 and 29th August 1953" state the serious situation that now prevails in the U.K.:—

#### *The Nation's Drug Bill:*

"The serious view that the Government takes of the rising drug bill is well demonstrated by the fact that Mr. Ian Macleod, the Minister of Health, attended in person the Annual Conference of Local Committees of the British Medical Association in order to appeal for the support of the medical profession in his efforts to reduce the unruly item without disciplinary action. He described the rising cost of the drug bill as one of the gravest and most urgent problems that confronted the National Health Service. He said that the exchequer could not go on paying an annual bill of something like 40 million pounds for drugs prescribed by general practitioners (when the whole range of dressings and appliances prescribed is considered, the figure is nearer 60 million pounds) unless the drugs were all essential for the proper treatment of patients."

"He advanced two major reasons for the increase in the drug bill from £31,500,000 in 1949-50 to an estimated figure of £46,500,000 in 1953-54 (1) an increase in the total number of prescriptions dispensed, over 200 million a year (the latest figures just announced are those for August 1952: 12,953,542 at a total cost of £2,709,428, or an average of 50.2d per prescription) and (2) an increase in the average cost of prescription from 2s. 9d. in 1948-49 to an estimated 4s. 3d. in 1953-54, due to (a) the introduction of new valuable but expensive drugs, (b) the rise in the ingredient prices until this year, though some drugs, e.g., some of the antibiotics, were considerably cheaper, and (c) the prescribing of an increased proportion of proprietary preparations in 1952, proprietaries represented 26 per cent. of the total number

of prescriptions, 52 per cent. of their total ingredient cost, and 44·5 per cent. of their total cost)."

"He quoted a few examples of how widespread prescribing of proprietary, as opposed to official (or standard), preparations was pushing up the drug bill. One was a proprietary reducing preparation, which if prescribed by its standard name, would have produced a saving of about £2,42,000 in 1951. The second included proprietary tablets containing aspirin, acetophenetidin, and codeine, which cost 6s. 3½d. for 50, compared with 2·11d. for 50 of the comparable standard preparations. The third was proprietary asthma inhalants, which might cost four to six times as much as a standard inhalant, with no evidence that there was anything to choose between proprietary and standard preparations from the point of view of therapeutic efficacy. It has been estimated that a sum of around £50,000 could be saved if comparable standard preparations were used instead of proprietary preparations in the treatment of peptic ulcer and heart diseases."

"The Minister then proceeded to indicate that practical ways in which practitioners could assist him in reducing this expenditure on drugs: (1) they could make more careful use of "National Formulary" preparations by referring to the two tables of proprietary preparations in the "Formulary" (those for which an identical preparation is available in the "Formulary" and those for which there is a "Formulary" preparation substantially the same or reputed to have an analogous therapeutic effect) and always prescribe a "Formulary" preparation unless there was special reason to do otherwise. Incidentally, the Minister points out, the "Formulary" preparations were recommended by experts of the medical and pharmaceutical professions (quite independently of the Ministry of Health) and there was no reason to regard them as inferior simply because they were cheaper; (2) Practitioners could satisfy themselves before prescribing a proprietary preparation not included in the two "Formulary" lists that there were adequate grounds for accepting its therapeutic value in treating the particular condition for which it was prescribed; (3) Practitioners could resist pressure from patients to prescribe particular preparations that had been recommended or that they had read about in technical or semi-technical journals; (4) Practitioners could also refrain from prescribing unreasonably large quantities of a drug or dressing."

"The steps being taken by the Ministry included the issuing of a price list of "Formulary" preparations and proprietary preparations listed in the "Formulary" occupying a high place on the basis of frequency of prescribing. Physicians would thus be made fully aware of the cost what they were prescribing. In addition, there would

shortly be published the Cohen Committee's classification of proprietary preparations. This would enable Physicians to be told the names of preparations in the two "doubtful" categories covering drugs that were not of proved therapeutic value and might not be prescribed. Simultaneously the Ministry was proceeding, in consultation with the manufacturers, to investigate the production costs of selected proprietary preparation in the categories that the Cohen Committee considered prescribable subject to satisfactory price arrangements."

"While the problem may be a relatively simple one from the point of view of the Minister of Health, the implication if he succeeds in his economy drive are far from simple. One of the most serious implications is the effect on the research budgets of the leading pharmaceutical houses. The Minister has consistently paid tribute to the considerable amount of research done by these companies, but he has tended to take the line that his major interest is the drug bill and that research and, incidentally, export sales are not his responsibility. That the pharmaceutical companies are becoming worried about the future of their research departments is well brought out in the recently published annual report of the Chairman of the company owning the largest chain of retail pharmacies in the United Kingdom. According to the *Pharmaceutical Journal*, this chairman "declares that unless British firms are allowed to recover the cost of research in the products they sell, they cannot continue to spend money on research. This could only mean that more and more specialities would have to be brought from abroad, principally the United States and Germany, where immensely more money is spent on research than in this country.....If the Minister's plans result in the Service becoming unremunerative to the pharmacist on the present terms then the dispensing fee must be raised to keep him on an even financial keel."

#### *Prescribing of proprietaries:*

"Almost coincidentally with the fifth anniversary of the inauguration of the National Health Service, the first steps have been taken in the Ministry of Health's campaign to reduce the national drug bill by prescribing proprietary medicine. The build-up of this offensive goes back to 1949, when there was established a joint committee on prescribing of the Central and Scottish Health Services Councils to "consider the report from time to time whether it is desirable and practicable to restrict or discourage the prescribing by practitioners giving general medical services under the National Health Service Acts of 1946 and 1947, of (1) drugs and medicines of doubtful value or of unethical character; (2) unnecessarily expensive brands of standard drugs." In June 1950, the

Committee presented an interim report, the gist of which was that proprietary preparations could conveniently be arranged in six categories: (1) New drugs of proved value not yet standard; (2) Proprietary brands of standard drugs, singly or in combination; (3) Standard preparations, and new remedies of proved value, in elegant form or vehicle; (4) Qualitative and/or quantitative modifications in the composition or combination of standard preparations, or new remedies of proved value, that are not accepted as therapeutically superior to preparations included either alone or in combination in the British Pharmacopoeia, the British Pharmaceutical Codex, or the National Formulary, (5) Preparations not in the British Pharmacopoeia, British Pharmaceutical Codex, or the National Formulary, which in the Committee's view have not been proved of therapeutic value; and (6) preparations that are a combination of (4) and (5). The Committee recommended that proprietary preparations in category (1) should be "freely prescribable", and that those in categories (2), (3) and (4) should be prescribable provided they were not advertised to the public and provided satisfactory arrangements for pricing could be made between the health departments and the manufacturers. Categories (5) and (6) were dealt with as follows: "Apart from preparations in categories (5) and (6).....we have no reason for suggesting on medical grounds that these proprietary preparations should not be freely prescribable in the National Health Service except when advertised to the public."

"This report having been accepted, the committee then proceeded to classify proprietary preparations according to the six categories. During the last 2½ years, the committee has reviewed some 5,000 preparations, and 800 of these have been placed in categories (1), (5) or (6). A list of these 800 preparations has been sent to every physician taking part in the National Health Service. This list shows that 150 preparations have been placed in category (1) and 650 in categories (5) and (6). It is stated that preparations not shown in this list may be assumed to fall into categories (2), (3) and (4), until supplementary lists are issued. The bulk of the preparations placed in categories (5) and (6) consist of polyglandular oral preparations, enzyme preparations, such as diastase and pepsin, some metallic collodidal preparations, oral vaccines, chlorophyll tablets, and epinephrine (Adrenaline) cream."

"In a covering letter, the chief medical officer of the Ministry of Health asks practitioners not to prescribe preparations in categories (5) and (6) and "only to prescribe preparations not included in the enclosed lists after you have ascertained the cost and compared it with that of identical or similar standard preparations and not to prescribe preparations of which the price is not readily and conveniently ascertainable." He adds:

"Obviously what I have said is without prejudice to your right to prescribe whatever you think necessary in any individual case but a general practitioner may, of course, be called on to justify the cost of prescribing to his colleagues on the Local Medical Committee". Such veiled threats are anathema to a liberal profession, but they seem to be inevitable accompaniment of a government controlled service. On the other hand, it is only fair to point out the few, if any, of the banned preparations are any loss to treatment. Even the Association of British Pharmaceutical Industry can find no real grounds for criticism of the classification on this account."

5.3. Attempts must be made to see that such exigencies do not arise in India. Only a few standard combinations are valuable and should be permitted. As in the U.K., a Committee of experts on which the Government, Indian Medical Association and the Industry are represented should prepare a list of standard combinations, which are considered essential and which should be allowed to be manufactured or imported. The expert body already suggested by the Committee in Chapter IV may be entrusted with this work.

5.4. There has been a consensus of opinion among the medical profession that in some form or other, a national formulary should be formulated so that unnecessary and useless preparations are not put in the market. The Committee however feel that the stage for the preparation of this formulary is not yet ripe and that this matter may be held over till the Indian Pharmacopoeia is published. After its publication the expert body suggested above, may be given the task of preparing a national formulary. Attempts in this direction have already been made in the State of Madras and Bombay where the Government have published a 'General Hospital Formulary' which gives various standard prescriptions which are used in all Government and local-fund medical institutions. It is suggested that a similar procedure may be adopted for the use of various institutions in other States of India.

## **6. Medical Practitioners and Dispensaries:**

6.1. The general practitioner who runs a dispensary uses individual drugs and compounds them into a suitable mixture, powder, pill etc., and dispenses them to his patients. He also does dressings, carries out minor surgical operations and gives injections. In most of the cities in India, the charges for the mixtures, powders and pills include a consultation fee as no additional charge is made for it. During the last ten years or more, there has been a radical change in the matter of dispensing. The pharmaceutical industry is providing elegant prescriptions, compounded tablets, pills, powders ointments etc., all ready for administration. The dispensing work has therefore diminished. The cost of these readymade preparations is high. The margin left to the doctor as consulting fee is low.

6.2. Time has now definitely arrived especially if medical men are not to become retail traders when a fee for first consultation and a proportionate one for subsequent attendances will have to be charged to the patient.

6.3. Except for routine mixtures, powders or ointments, no ready-made compounded drugs should be sold by the practitioners to his own patients. The charges for the dispensed medicines should be minimum. The retail chemist should supply all drugs which are ready for consumption; the retail chemist should on his side, not sell medicines except a recognised few, unless a doctor has prescribed them. If this is followed, a healthy co-operation will spring up between medical men and the pharmaceutical trade.

6.4. The burden of maintaining a dispensary and to a certain extent becoming retail chemist should be removed from the doctors. Of course, in areas, where no pharmacists are available, the doctor will have to continue doing both as at present. The position aimed at is, however, the ideal one but for some time to come, the private practitioners may be allowed to have their dispensaries to dispense only to their own patients. It must be understood that when pharmacies are maintained by private practitioners, they must be subjected to the same rules and regulations of the Drugs Act as the chemists and pharmacists.

## 7. Labels:

7.1. The medical profession unanimously favour the chemical name or its recognised abbreviation (International Pharmacopoeial) or an agreed name to be printed on the labels as well as in the advertisements published in Medical or their own journals first in large letters, firm name to go with it in the same line, if space permits, or below it, and the patent or trade name below these, if the industry insists on them. The Committee, however, feel that the recommendation regarding rigid enforcement of Rule 109(1)(a) of the Drugs Rules made in Chapter V will go a long way in solving this problem.

सत्यमेव जयते

## CHAPTER IX

TECHNICAL TRAINING FOR THE PROFESSION OF  
PHARMACY

## 1. Status of the Profession:

1.1. The Pharmacists have a vital role to play in the health services of a country. This is being increasingly recognised in advanced countries, and the profession of pharmacy enjoys a high status in U.K., U.S.A., Switzerland and France. Unfortunately, in this country the retail drug stores and pharmacies are mostly in the hands of people, who have had very little education leave alone education in pharmacy. They are not bound by the ethics of the profession and their main aim is to get rich quickly without reference to the means employed for the purpose. They do not maintain adequate premises and equipment required for carrying on the trade and dispensing medicines and rarely employ qualified pharmacists. If all the establishments dealing in drugs and dispensing medicines were manned by qualified pharmacists, there would be very little scope for trade in spurious or sub-standard drugs. The equipment and other facilities would be maintained at the desired level and the drugs purchased through proper trade channels, from manufacturers, importers, wholesalers and not through intermediaries, whose integrity is open to doubt. The requisite background knowledge of the laws relating to the profession stand them in good stead, while scrutinising the labels and packings of drugs and recognising faked drugs from real ones. Similarly, if this important job in the hospitals and dispensaries throughout the country is under the supervision of competent pharmacists, the existing feeling of distrust, which prevails in the minds of the public about the quality of drugs dispensed by these institutions would be removed. The Government and pharmaceutical trade should, therefore, try to build for the profession of pharmacy a recognised place in society by improving the standard of education of pharmacists and by regulating the profession. With the introduction of the Drugs Act and the Pharmacy Act, there has been some improvement in the status of the profession of pharmacy; but still a lot more has to be achieved, before it can be organised on sound lines.

1.2. The profession of pharmacy in this country is mostly represented by a set of people known as compounders, whose status, functions and duties are ill-defined and improperly understood. They carry on the compounding, dispensing and sale of drugs including poisons in the private pharmacies and in hospitals. Their pharmaceutical education is deplorably inadequate and the majority of them employed in the trade have had none at all. Compounders employed by government hospitals and dispensaries have been given some training, the standard of which varies from one State to another. Two types of training have been made available in the



country, (i) compounders or dressers; and (ii) chemists and druggists. The period of training for compounders varies from one to two years and the preliminary qualifications demanded in different States are not uniform but low. In some cases, the completion of the middle school examination, while in others, the completion of high school education, have been prescribed. But very often, even these low standards of educational qualifications have not been insisted upon. In many a State the profession of pharmacy has been the last resort of those, who could not complete their high school education or who were found to be intellectually unfit for any other career. Owing to the poor background of education of the candidates, the quality of training imparted, particularly with reference to poisons, the study of their dosage and incompatibilities etc., can be better imagined than described. In the States of Bengal and Madras, the pharmaceutical education imparted has been of a comparatively higher standard, the Chemists and Druggists' Diploma granted by the Government of Madras being the best course of study in pharmacy in the early days both in regard to the quality of training as well as the syllabus.

## **2. Drugs Enquiry Committee and Bhore Committee:—**

2.1. The Drugs Enquiry Committee, drew the attention of Government in their Report published in 1931 to, this deplorable state of affairs in the profession of pharmacy, the inadequate facilities available for the training of compounders, and the continued danger to the health of the public by allowing persons not well qualified both in academic training as well as professional training to carry on the profession of pharmacy. They recommended legislation to regulate the education and the profession of pharmacy. Comprehensive measures were suggested in the report for registering the practising pharmacists and to bind them to a prescribed code of ethics. They also suggested detailed courses of study for adoption for pharmacists, and institutions where such courses could be conveniently started.

2.2. Eight years after the publication of the report of the Drugs Enquiry Committee, the Health Survey and Development Committee popularly known as the Bhore Committee also focussed the attention of Government to the little or no improvement that had taken place and the need for a thorough overhaul of the profession of pharmacy in the country. The Bhore Committee, among others, recommended, (i) the establishment of an All-India Pharmaceutical Council and Provincial Pharmaceutical Councils representing the pharmaceutical trade, education and other pharmaceutical interests, (ii) enactment of legislation designed to protect the public from incompetence and to safeguard the interests of qualified pharmacists to raise the professional standing of pharmacists engaged in the handling of drugs, (iii) measures for registration of pharmacists, (iv) measures for maintaining disciplinary control over the practice and profession of pharmacy and (v) revised courses of study for pharmacists.

## **3. The Pharmacy Act:**

3.1. As a result of these recommendations and articles published in journals devoted to the cause of pharmacy and pharmacists by

a few pioneers in the field, the Government of India enacted in 1948 the Pharmacy Act. This Act provides for the establishment of a Central Pharmacy Council of India comprising of the representatives of the pharmaceutical trade, education, and other pharmaceutical interests including the representatives of registered pharmacists from the States and nominees of State Governments. The functions of this Council are two-fold, namely, to prescribe the minimum standard of education required for qualification as a pharmacist and to inspect and approve of institutions providing courses of study in pharmacy. All such institutions have to be approved by this Council in order that persons completing the training in such institutions or holding the qualifications granted by them may be eligible for registration as pharmacists. The Executive Committee of the Council is empowered to appoint inspectors for the purpose of inspecting the institutions.

3.2. The registration of pharmacists under the Pharmacy Act has been entrusted to the State Pharmacy Councils. Conditions are laid down for the preparation of register and details of qualifications for entry on the first register and for subsequent registration are also specified. The State Pharmacy Councils have been made responsible for the maintenance of disciplinary control over the profession of pharmacy. A penalty is prescribed to anyone who falsely claims to be a registered pharmacist or uses to describe any premises in the terms "Pharmacist", "Chemist", "Druggist", "Dispenser", "Dispensing Chemist" or any other term, calculated to suggest to the public, that he is a registered pharmacist.

3.3. It has also been laid down that after a certain date to be notified by State Governments, no person other than a registered pharmacist shall dispense medicine on a prescription from a registered medical practitioner, excepting medical practitioners dispensing medicines for their own patients or in special cases, for the patient of another medical practitioner.

#### 4. The Pharmacy Council of India:

4.1. The first Central Pharmacy Council of India was constituted on 9th March 1949. This Council has already prepared and published the Regulations prescribing the minimum standard of education required for qualifying as a pharmacist. These Regulations also lay down the requirements in regard to equipment, accommodation, staff etc. of institutions which provide courses of training in pharmacy and also the nature and extent of practical training which pharmacists should undergo after completing their academic course. The "Intermediate in Pharmacy" and "Bachelor of Pharmacy" courses of study provided by the Birla College, Pilani have been approved as conforming to the Education Regulations and hence accepted as approved courses of study for the purpose of admission to an approved examination of pharmacists. The State Governments have been requested to take early steps to start at least one model institution for providing courses of study for pharmacists in accordance with the Education Regulations prescribed by the Pharmacy Council of India in each State. It is hoped that the State Governments and Universities which have already started such courses of study in pharmacy for entry into the profession will

review the facilities available for training and bring them in conformity with the Education Regulations prescribed by the Pharmacy Council of India. It is reported that so far no State Government has approached the Central Pharmacy Council for approval of the courses of study for pharmacists conducted by them.

4.1.1. The Education Regulations have not become operative in any State so far, but according to the provisions of the Act they will take effect in the States on the expiry of three years from the date of the constitution of the State Pharmacy Councils unless they are declared as having taken effect earlier by the State Government concerned. The first register of pharmacists have been published by most of the Part 'A' States.

## 5. Degree Courses in Pharmacy:

5.1. To impart a higher grade of training comparable to the graduate pharmacists or pharmaceutical chemists found in Europe and America, degree courses were started first by the Banaras Hindu University in 1934, and followed by other universities. A full fledged College of Pharmacy has come into existence in Ahmedabad. The University of Bombay has started a course in B.Sc. (Tech.) for specialising in pharmaceuticals to meet the needs of the Industry. All these courses in university education in pharmacy are outside the scope of the Pharmacy Council. The Pharmacy Council of India which, at present, lays down the minimum registrable qualifications for pharmacists should also lay down minimum standards for Degree Courses in Pharmacy. Such Degree Courses, at present adopted by various Universities should conform to the minimum standards laid down by the Pharmacy Council of India.

5.2. It has been represented to the Committee that the courses of study prescribed for practising pharmacists should be co-related with the university education in pharmacy so that registered pharmacists might be in a position to take up the graduate degree in pharmacy with a view to bettering their prospects in the profession. This it is contended will provide an incentive to those who cannot otherwise afford the expensive university degree courses to become a pharmacist, earn some money and collect funds to continue the education in the university for the degree course and if necessary even the post graduate course. They desire that the courses of study prescribed by the Pharmacy Council for pharmacists should be drawn to be acceptable by the Inter-University Board as equivalent to the 'I. Pharm' Course. Like the Rajputana University which has started an "I. Pharm" Course, they desire that other universities should be persuaded to start similar courses which should be acceptable to the Pharmacy Council for registration as a pharmacist. This is a subject which needs careful study by the Board of Technical Education.

5.2.1. It is desirable to have uniform minimum standard of education in the different universities to enable students to go from one university to another and enter the course at an appropriate stage. The Inter-University Board's help and co-operation should be sought in achieving this purpose. Provision for post-graduate training should be made in different branches of pharmacy in the various universities.

## 6. Improvement of Pharmacy in India:

6.1. Much has been done to improve the status of the profession of pharmacy during the course of the last few years. Yet without belittling all these efforts, it can be stated that considerable leeway has still to be made for the profession of pharmacy to be organised on a sound basis. Some broad lines indicating future course of action are recommended below for accelerating these efforts:—

6.1.1. The Pharmacy Act should be made operative uniformly throughout the country by extending it to all the States of the Indian Union.

6.1.2. The Pharmacy Council should be empowered to draw up a code of ethics for the profession of pharmacists which should be enforced rigorously.

6.1.3. The standards of education prescribed by the Pharmacy Council should not be relaxed.

6.1.4. It is found that there are no provisions in the existing legislations for controlling the practice of pharmacy. It is well known that most of the pharmacies in this country do not have even the minimum equipment necessary for carrying on the profession of pharmacy. A list of minimum equipment and reference books necessary for the efficient running of a pharmacy should be drawn up and enforced. A tentative list drawn up by the Committee is given in Appendix No. 14.

6.1.5. When the profession of pharmacy is organised and when a minimum standard of education and training has been prescribed for it, it should be made sure that no in-roads are allowed to be made into the legitimate field of work pertaining to this profession. Of late, medical practitioners have, in most of the towns and cities, started their own dispensaries, thus depriving the practising pharmacies of their legitimate business. The pharmacists in the country have been strongly urging that medical practitioners should be asked to stop the practice of running dispensaries. Judging from the nature of pharmacies run by most of the medical practitioners and the type of personnel that are placed in charge of them it appears that the pharmacists are justified in their views on this question. What is more, in several states, such as Bengal etc. practising medical practitioners are understood to have been registered as pharmacists in the first register. Dispensing of drugs should ordinarily be done by pharmacists. A person should be allowed to enrol either as pharmacist or as a medical practitioner but not both. Medical practitioners may, however, be allowed to dispense drugs to their own patients. The medical practitioners should, as far as possible, employ qualified persons to do the dispensing work.

6.1.6. The Pharmacists have also been complaining that medical practitioners have been enjoying certain special privileges under the Drugs Rules. These privileges are abused by some medical practitioners, and the result is widespread resentment among the chemists and druggists. The question of requirements for a general practitioner in maintaining his dispensary in the proper way, should be examined by the State and Central Medical Councils. It should be considered necessary for them to maintain minimum equipment

and requisite storage arrangements and adequate maintenance of proper records on the lines of those provided under the Drugs Rules.

6.1.7. There is an unfortunate tendency in government departments to assume that pharmacists will not be able to manage their own affairs. As a result of this, it is seen that the members of the medical profession have been given increased weightage on the statutory bodies constituted under the Pharmacy Act and other allied legislations. The pharmacists throughout the country are gradually organising themselves into bodies aimed at raising the status of their profession and they consider that the excess weightage given to the medical profession in the Central and State Pharmacy Councils tantamount to unnecessary interference in their domestic affairs. As a reprisal, certain pharmaceutical associations have even gone to the extent of demanding complete withdrawal of representation given to the medical profession in the Central and State Pharmacy Councils. The profession of pharmacy is just coming of age and it is necessary for its members to realise that they would be doing a positive disservice to themselves if they do not maintain harmonious relationship with the members of the sister professions. The medical profession, too has to recognise the importance of the pharmaceutical profession and should cease to be overbearing in its behaviour towards pharmacists. The medical and pharmaceutical professions should organise themselves in such a manner as to foster a spirit of amity and mutual co-operation by inviting the representatives of one profession for the conventions and meetings of the other profession.

6.1.8. It is not enough, if the Pharmacy Act is extended on paper to all the States in the country. Excepting for a very few States, the progress made by other States in the enforcement of the Drugs and Pharmacy legislation has been very poor. The State Governments have not realised the urgent need for starting institutions for providing courses of study in pharmacy. At least one model institution has to be started in each State. In addition, a Central Institute of Pharmacy should be established under the auspices of the Central Government. It is the common feeling among the members of the pharmaceutical profession and the drug trade that the interests of pharmacists and the various questions relating to the enforcement of the Drugs Act do not receive adequate consideration at the hands of medical officers, who are usually entrusted with the task of administering these legislations in the States. Not only should State Governments appoint qualified pharmacists or chemists who are well aware of the nature of problems facing the pharmacists and the drug trade as officers responsible for administration of these Acts but they should also be guided by the views given by responsible pharmaceutical associations.

6.1.9. It is necessary for Government and Trade to take concrete steps to raise the status of the pharmaceutical profession. The former should remove from the minds of the public the mistaken impression that the profession can be carried on by persons who have no background in academic and professional training. The public should be made to realise that the pharmaceutical profession is a dignified one. As the first step towards building up the prestige and status of the profession the State and Central Governments

should increase the scales of pay applicable to pharmacists. The scales of pay that are applicable to pharmacists in the Centre and States should be upgraded wherever they are low. A minimum scale of pay of Rs. 80—5—120—EB—200—10/2—220 should be given to those pharmacists who are Matriculates and are eligible for registration under the Pharmacy Act. To provide necessary incentive for work, a selection grade carrying a scale of pay of Rs. 160—10—300—EB—15—450 should be created.

6.1.10. Besides these measures, chief pharmacists for all large hospitals should be graduates in pharmacy. The savings that would be effected by the hospital pharmacists in running the pharmacies would be considerable.

6.1.11. Finally, Government should enlist the support of responsible pharmaceutical associations in their campaign to raise the status of pharmacists. Such bodies can do more to instil in the minds of the members of the profession a sense of discipline and an awareness of the code of ethics of the profession than what Government can hope to do through its own efforts.



सत्यमेव जयते

## SUMMARY OF RECOMMENDATIONS

### CHAPTER I—INTRODUCTION

### CHAPTER II—PHARMACEUTICAL INDUSTRY—ITS SCOPE AND DEVELOPMENT

#### *Scope of the Industry.*

1. Each manufacturing concern should endeavour to produce as many fine chemicals and drugs starting from basic chemicals, and/or intermediates as close to the basic chemicals as practicable for the time being, in quantities sufficient to meet, not only its own requirements but also of other firms which process them. By such co-operation between different units and the pooling of their resources, the pharmaceutical industry will undergo rapid development.

(2.5.)

2. Some processing firms prefer to import their supplies of fine chemicals or intermediates rather than purchase from firms which have undertaken their production in the country. On the other hand, certain firms which are endeavouring to produce these fine chemicals and intermediates do not wish to supply them to others for processing. Such lack of co-operation between the firms should be thoroughly discouraged and a radical change in outlook brought about for fostering a healthy development of the industry. Government should actively encourage co-operation between the two sections of the industry and, wherever required, even sponsor the manufacture of fine chemicals and drugs to bring about a co-ordinated development of the industry.

(1.6.)

#### *Government Medical Stores.*

3. The manufacturing activities of the Government Medical Stores should be reorganised and their method of management changed to conform to commercial practices. Antiquated equipment should be replaced by modern equipment and in addition to the existing manufacturing activities, production of essential items including fine chemicals which are not being adequately made by the private sector, should be taken up. The choice of new products should be made taking into account the existing facilities at these depots such as availability of raw materials, power, markets etc.

(2.7.2.)

4. We observe that there is considerable delay in the supply of indents placed on the Stores by State Governments and other bodies, and also that the prices are high owing to heavy overhead charges. To remedy the position, we recommend that the Stores activities should be handed over to the respective State Governments, consistent with the commitments of the Central Government.

(2.7.1., 2.7.3., & 2.7.5.)

5. In case, the State Governments are not in a position to take over the Medical Stores, the Committee do not see much future for their Stores activities and feel that there may be no choice but to close them down.

(2.7.5.)

### *Opium Factory*

6. Experimental plantations should be set up (i) for investigating methods for improving the yield of opium; (ii) to render technical advice; (iii) to supply better grades of seeds; and (iv) to demonstrate improved methods of cultivation to the opium cultivators.

(3.3.)

7. All unit operations such as, mixing and bricketting which are, at present, carried out manually should be mechanised.

(3.4.2.)

8. The methods adopted for processing the crude opium should be directed towards improving its quality, such as uniform moisture content, elimination of impurities, improved alkaloid content etc., which will enhance its value for use in medicinal and industrial purposes, and not to cater to the tastes of opium addicts.

(3.4.3.)

9. Commercial methods of marketing the different products of the factory should be adopted. The products should be advertised in Indian and foreign scientific and trade journals, for developing wider markets, and thus ensure its economic production.

(3.4.6. & 3.4.7.)

### *Penicillin Factory—(Hindusthan Antibiotics Ltd.)*

10. A well-equipped research laboratory, and a pilot plant, should be set up for carrying out investigations side by side with manufacture to keep pace with the rapid developments in the field of antibiotics. The pilot plant will help to work out the optimum conditions for operating the main plant, without having to carry out large scale trials on the main plant itself which will be expensive.

(4.4.)

11. The penicillin factory under installation at Pimpri is designed to produce ultimately 9 million mega units of penicillin annually against the country's estimated requirements of approximately 20 million mega units. It is reported that the proposed capacity could be further increased to 15 million mega units with the use of improved strains of penicillin mould without any major modifications to the plant. Although, a major portion of the demand would be ultimately met, the demand is likely to increase further by the time this production is actually achieved. The Government should, therefore, encourage the private sector to fill the gap or increase the capacity of this factory.

(4.5.)



12. The manufacture of other antibiotics particularly streptomycin should be also undertaken in the proposed penicillin factory. If it is not possible for Government to produce the entire estimated demand of 10,000 kg. of streptomycin at this factory, the private sector should be encouraged to produce the balance.

(4.6.)

13. As the manufacture of penicillin needs certain chemicals, whose production will have to be undertaken at Pimpri, it will be economical to extend the activities of the penicillin factory to include the production of synthetic antimalarials, sulpha drugs, other chemotherapeutic products and vitamins. The manufacture of all these products at this factory will also help to establish a centre for the manufacture of several essential chemicals at one place.

(4.7.)

*D.D.T. Factory—(Hindusthan Insecticides Ltd.)*

14. A research unit and a pilot plant should be provided in this factory to carry out investigations on the production of new type of insecticides and conduct experiments on their production.

(5.3.)

15. The production capacity of the factory under installation at Delhi is 700 tons per annum against the country's estimated annual requirements of 8,000 tons of insecticides such as B.H.C. and D.D.T. The capacity for B.H.C. and D.D.T. either in existence or expected to come up shortly is 2,000 tons. The Government should encourage the private sector to manufacture the balance or should themselves put up a second unit for its production in any suitable place in the country where the required raw materials and power are available.

(5.4.)

*Madras Cinchona Plantations and Quinine factories.*

16. The programme of replacing the existing plants with those whose bark yields a higher quinine content should be accelerated.

(6.5.3.)

17. The factory at Naduvattam should be improved by replacing the antiquated equipment by modern equipment and adopting modern methods of manufacture. Mechanisation of the factory on modern lines, coupled with the higher quinine content in the bark, will considerably help in bringing down the cost of production and thus be in a position to compete with synthetic antimalarials, and imported quinine.

(6.5.4.)

18. The design and lay out of the new factory under construction at Anamalai leaves scope for improvement. For more efficient working of the factory, certain alterations would be necessary. A rearrangement of the existing equipment, and mechanisation of certain operations, now designed to be carried out manually, should be undertaken with the help of suitable chemical engineering firms experienced in such work.

(6.5.6.)

19. Sufficient attention has not been paid by the Madras Government for providing elementary amenities, like electricity for lighting the quarters, to the staff of the Cinchona Department stationed in the plantations. Every amenity should be afforded to the staff especially as they are living in isolation without any social contacts.

(6.5.7.)

*Bengal Cinchona Plantations and Quinine ractory.*

20. Some of the operations now carried out manually like the transport of the mixture of bark powder and lime for lixiviating with caustic soda solution in tanks, should be mechanised.

(6.6.3.)

21. The programme of replacing the existing cinchona plants with those whose bark yields a higher percentage of quinine should be accelerated.

(6.6.4.)

*Assam Cinchona Plantations.*

22. The cinchona plantations in Assam are not so well developed as those in Madras and Bengal. We understand that the soil and climatic conditions are not favourable. As the Special Cinchona Committee have advised against any expansion of the existing plantations in the country, in view of the uncertain position of quinine, the Assam Government should not spend their finances and energies in expanding these plantations specially when the State is endowed with all the natural advantages for cultivating other medicinal plants for which a great shortage exists in the country.

(6.7.1.)

23. For an estimated production of 5,000 lbs. of processed quinine per annum, the setting up of a factory, as proposed, would be uneconomical specially with the poor cinchona plantations that exist in the State.

(6.7.1.)

24. The possibility of sending the bark for processing at the Quinine Factory at Mungpoo which has at present a surplus capacity should be explored.

(6.7.1.)

*Assistance to Quinine Factories.*

25. Commercial methods of marketing quinine should be adopted by the Governments concerned. Dumping of foreign quinine into the country should be prevented. Customs duty should be imposed on synthetic antimalarials and foreign quinine.

(6.8., 6.8.2. & 6.8.3.)

26. For the disposal of accumulated stocks of cinchona febrifuge, the State Governments, the District and Local Boards and other bodies should be requested to use this product to meet a part of their requirements of antimalarials. A general appeal in this connection should be sent to these bodies.

(6.8.4.)

### *Shark Liver Oil Factories.*

27. The two State Governments (Bombay and Madras) are competing with each other in the sale of their products and trying to obtain the raw materials at as cheap a price as possible from the local fishermen to whom has been entrusted the work of catching the sharks. By unregulated fishing, a very valuable source of vitamin 'A' may be lost to the country. The Central Government should, therefore, look into this matter urgently and see that necessary steps are taken for conserving this important source and bring about a better co-ordination in its exploitation by the two state Governments.

(7.8.)

28. The manufacturing and marketing activities of the two State Government factories at Bombay and Kozikhode should be co-ordinated. A uniformity in quality and packing and a common brand name instead of calling them differently as "Madras Government Shark Liver Oil" and "Bombay Government Shark Liver Oil" should be adopted by the two factories.

(7.9.)

29. They should endeavour to adopt (a) a uniform selling price for the different grades, (b) scale of discount to traders and (c) a common publicity for the products made. If necessary, the territories, where their products should be marketed can be defined by the two governments.

(7.9.)

30. The selling prices fixed by the Bombay Government for the products of their Shark Liver Oil Factory give a greater margin of profit to the distributor than to the retailer. Normally, it should be the reverse. The profit margin should, therefore, be rationalised.

(7.4.1.)

### *Other Government Institutions.*

31. The production of hyperimmune rabies serum in institutes like the Haffkine Institute, Bombay, where facilities for its production exist should be taken up in adequate quantities to meet the needs of the country. All schemes for its production should be actively assisted both by the Central and State Governments. For eradicating the danger of rabies in the country, the production of Avianised Rabies Vaccine at the Haffkine Institute should be increased and the vaccine made more easily available.

(8.2.)

32. Whooping cough vaccine is at present mainly imported and the diphtheria and tetanus vaccine are not being produced in adequate quantities in the country. The Haffkine Institute, Bombay has carried out experiments on the production of whooping cough vaccine and its scheme for its production should be actively encouraged. Steps should be taken to increase the output of diphtheria and tetanus vaccines. An attempt should be made to manufacture the triple vaccine required for the simultaneous prophylaxis of vulnerable groups of population against these diseases.

(8.4.)

33. It is necessary to keep facilities for the production of influenza vaccine ready at hand to meet emergencies. The Haffkine Institute has carried out experiments for the production of this vaccine and its scheme should be actively encouraged.

(8.5.)

34. The supply of antivenine serum from the Government Institutions producing it, is restricted to hospitals and aided institutions only and therefore not easily available to the public in emergencies. This serum should be made easily available to the public by allowing it to be purchased and stocked by retail chemists and druggists. The Government should afford the necessary facilities to the Haffkine Institute, Bombay, to expand the snake farm and increase its out-put, and other institutions should be encouraged to start snake farms and produce the serum.

(8.6.1.)

35. At present, the vaccines and sera made by the Government institutions are only available at Government hospitals. This practice should be revised and the products made available to the general public through the retail trade by adopting commercial methods of marketing.

(8.6.2.)

36. Besides manufacturing sulphathiazole, the Haffkine Institute has finalised schemes for the production of certain other sulpha drugs and synthetic antimalarials like Proguanil Hydrochloride (Paludrine). But these schemes have not been put into effect as the management of the Institute feel that the manufacture of chemicals is not in keeping with its main activities and involves chemical processes for the supervision of which they have not been suitably equipped. As the Government have participated in the manufacture of these essential products and helped at a time to stabilise prices when supplies were scarce in the country, the Committee feel that this activity should not be closed down. The Institute is willing to hand it over to any Government Organisation better suited for the supervision and management of the manufacture of synthetic drugs. The possibility of transferring their present activity in this respect to the Government Penicillin Factory at Pimpri should be examined. If this is not feasible, this section should be separated from the control of the Institute and run by the Bombay Government as a separate organisation.

(8.7.)

*Large Scale Private Enterprise under foreign control and/or foreign collaboration.*

37. The firms should progressively extend their manufacturing activities to include the production of bulk pharmaceuticals, starting from basic chemicals and/or intermediates as near to the basic chemicals as possible. The difficulty likely to be experienced in obtaining their supplies of raw materials should be overcome by allowing their imports freely until such time as their production capacity develops within the country.

(1.5.)

38. While planning the production of bulk pharmaceuticals the production capacity should not be confined merely to the requirements of the particular factory, but should be large enough to be able to supply, as far as possible, the requirements in the country.

(1.5.)

39. The size of an economic unit, as envisaged in foreign countries, does not apply *in toto* for conditions existing in India. Lack of sufficient demand at the moment to justify such economic units should not, therefore, deter firms from putting up units, for their manufacture within the country. Even if the demand for an essential product is slightly lower to warrant an economic production within the country, its production should be undertaken and the Government should give protection to the industry to withstand foreign competition, until such time as the demand rises to an economical level. The choice for the development of any such product should be left entirely to the manufacturers concerned depending on the facilities they possess for such development, subject to the approval by Government.

(1.5.1.)

40. No new foreign concerns should be allowed to set up factories unless they undertake to manufacture products which have not been manufactured in adequate quantities by other factories, starting from basic chemicals and/or intermediates as near to the basic chemicals as possible, within a reasonable time. To avoid unhealthy competition at the early stages of development, and to ensure the concerns sufficient off take to justify investments on such manufacture, only a few firms should be allowed to take up the development of the same product.

(1.5.2.)

41. Arrangements made by certain manufacturers, whether Indian or foreign, forbidding the selling of bulk chemicals to other processors based on agreements entered into with foreign firms should be discouraged.

(1.6.)

42. Certain arrangements which have been entered into between some manufacturers in India with firms abroad by means of which, the former are not in a position to undertake the manufacture of other useful and latest drugs, based on the original product (prepared in collaboration with the latter), are not in public interest and, therefore, should be discouraged.

(1.6.1.)

43. The Patent Laws of the country should be amended to secure effective utilisation of all developments in the field of science and medicine, wherever necessary in the interest of the country.

(1.6.2.)

44. Firms which have no processing departments of their own but get such work done at others' factories should be given permission to put their own departments for the purpose, provided that some of the drugs are of an essential nature and they undertake to produce these starting from basic chemicals and/or intermediates as

near to the basic chemicals as possible, within a reasonable time. Meanwhile, the utilisation of the existing processing capacity of firms which manufacture products for marketing by firms, owning or leasing trade marks, should be allowed to continue as at present. No further addition to it by Indian, foreign or semi-foreign firms should be allowed.

(1.7.)

45. In future, before permitting collaboration with foreign firms, Government should adopt the following guiding principles. The existing agreements should also be revised at the earliest opportunity to be in conformity with these principles:—

- (i) No foreign collaboration should be entertained only in respect of cosmetic items such as tooth pastes, eau-de-cologne, shaving creams etc.;
- (ii) Generally, foreign collaboration should be allowed only when a firm is agreeable to commence with the manufacture of at least a few basic drugs from primary raw materials;
- (iii) Permission may be granted for compounding of selected drugs on basis of essentiality provided the firm agrees to complete its programme of manufacture of basic drugs within a specified period; and
- (iv) The scheme of licensing should, as far as possible, be so evolved as not to give a monopoly to any one firm, but keep competition alive. In approving schemes for the manufacture of basic drugs, care should, however, be taken to see that the production of the same drug is not taken up by too many firms.

(2.8.)

46. The order of preference for foreign collaboration should be as follows:—

- (i) Products manufactured wholly in India from basic raw materials and/or intermediaries as near to the basic chemicals as possible of mainly Indian origin;
- (ii) Products for the manufacture of which the basic chemicals and/or intermediates as near to the basic chemicals as possible are imported;
- (iii) Products in which the finished drugs are imported in bulk and processed into pharmaceuticals here and packed; and
- (iv) Finished products imported in bulk and only repacked here for sale.

In future, there should be little scope, if any, for collaboration with any foreign concern of the type given under (iii) and (iv) above.

(2.9.)

47. In such cases, where imports of finished products like synthetic drugs, antibiotics, vitamins and hormones have to be maintained in view of their importance in the practice of modern medicine, such

imports should be gradually reduced and the existing processing capacity of the country should be utilised fully by importing them in bulk and processing them until their production develops in the country.

(2.10.)

48. Tie-ups with foreign firms including participation in capital should be preferred to "tie-ups" with no foreign participation in capital. In the pharmaceutical industry, however, foreign capital participation should not generally exceed 49 per cent.

(2.11.)

49. Firms with 100 per cent. foreign capital—the so-called "India Ltd."—and branches of foreign firms should not be permitted to be established except under special circumstances for the manufacture of basic chemicals and drugs, which the Indian managed factories are not able to take up. The desirability of insisting on participation of Indian capital, in cases where the manufacturing process is completed might be considered with a provision for repatriation of foreign capital from the sixth to the fifteenth year thereafter.

(2.11.1.)

50. No royalty should be paid on any product unless it has been included in the list furnished to and certified by the Ministry of Commerce and Industry that there is no current production of these items in the country and they would not become available except under a royalty payment.

(2.12.)

51. The manufacturing operations should be divided into the following categories:—

*Essential.*—Drugs like hormones, vitamins and antibiotics and also those used in the treatment and prevention of diseases; and

*Not Essential.*—Products like pick-me-ups, tonics, patent and proprietary medicines of a general nature, household remedies, tooth pastes, shaving soaps and talcum.

Royalty rates should be worked as under.—

*Essential:*.....Not exceeding 5 per cent.

*Not Essential:*.....Not exceeding 2 per cent.

(2.12.1.)

52. Payment of rates of royalty for "pure know-how" as agreed by some firms is excessive and this should be reduced to a reasonable figure, when current agreements come up for revision.

(2.12.2.)

53. Where royalties are to be paid for the manufacture of basic drugs, these should not be calculated on the value of the finished products but on the bulk basic drug.

(2.12.3.)

54. Payment of royalties for the exploitation of a registered trade mark or proprietary name should be discouraged. Where such royalties are paid, they should not exceed 3½ per cent. of the value of bulk

basic drug. In all cases, the royalties payable should be scaled down on the basis of the turn over as under:—

“Maximum agreed figure on net sales of Rs. 1,00,000 per year diminishing progressively year after year on sales upto Rs. 5,00,000 beyond which 2 per cent. should be fixed.”

(2.12.4.)

55. Generally speaking, agreements should be revised every five years, although in special cases, Government may permit agreement for a longer period initially.

(2.13.)

56. In future agreements, clauses which (i) prevent the purchase of machinery, raw materials or packing materials from the best available source; and (ii) restrict the sale of a drug manufactured under a royalty to any particular party or their nominee, should not be allowed.

(2.14.)

57. In all agreements, suitable provision should be made for training of Indian personnel.

(2.14.1.)

#### *Large Scale Private Enterprise under Indian Management:*

58. New firms should not be allowed to start the manufacture of galenicals for which there is already a surplus capacity.

(1.1.)

59. For better utilisation of the existing capacity of the firms and to prevent manufacture of sub-standard drugs, the equipment and staff employed by the firms should be scrutinised. Wherever the required minimum equipment and staff do not exist, the licence under the Drugs Act should be withdrawn.

(1.1.1.)

60. For extraction of alkaloids which are, at present produced in inadequate quantities, the manufacturing firms should be required to set up properly designed pilot plants and study the economy of their methods and collect sufficient chemical and chemical engineering data so as to enable them to design and set up plants for their extraction on a commercial scale.

(1.1.2.)

61. Many of the factories producing glandular products specially liver extract, vaccines and sera are not upto the standard required. The existing equipment for manufacture and testing should be scrutinised and licence under the Drugs Act withdrawn if proper equipment does not exist or where unhygienic conditions prevail.

(2.1.)

62. In the case of manufacture of fine chemicals and synthetic drugs, not so far manufactured in India and whose 'know-how' is not easily available, the firms intending to start production should be required to establish properly designed pilot plants with the help of standard chemical engineering firms and/or national laboratories



and collect basic chemical and chemical engineering data and study the economy of the methods to be adopted so as to enable them to put up large plants for their commercial production.

(3.2.)

63. To prevent firms producing the same or similar items, thereby creating unplanned expansion of the industry, all the firms should be asked to indicate their development programmes for the next 5 years along with the assistance they require from Government for carrying them out. These programmes should be scrutinised by Government and the firms allowed to take up development of such lines of production for which they are most suited ensuring simultaneously that important lines of production are being explored.

(3.2.1.)

64. Once a development programme of a particular firm has been approved, a constant watch on the progress made by it should be kept. The progress being satisfactory, all facilities should be given for its furtherance.

(3.2.2.)

65. A large number of firms should not be allowed to carry out almost identical type of work without due regard to the requirements of the country or the existing capacity as this will defeat the very object of the Industries, (Development and Regulation) Act and retard the development of the industry.

(3.2.4.)

66. Another factor which hinders the development of the synthetic drug industry is the working of the Patent Laws. The Government should consider if they can abrogate the International Patent Registrations to enable manufacturers in the country to take up the manufacture of essential pharmaceuticals like sulpha drugs, vitamins, hormones etc., without having to pay heavy royalties to foreign firms.

(3.3.)

67. At present, disinfectants and insecticides made in the country have no standards by which their effectiveness could be gauged. It is necessary to laydown standards for disinfectants and insecticides and bring them under the purview of the Drugs Act and thus control their quality.

(1.2.)

68. To prevent unhealthy competition and deterioration in the quality of products made, it is necessary to enforce strict quality control on the products marketed and withdraw the licence of the firms which do not keep up to the standards laid down.

(1.1.)

#### *Small Scale Private Enterprise:*

69. Government should take early steps to cancel licences and close down all pharmaceutical establishments which do not possess the minimum requirements of premises, equipment, and staff that the Committee have specified. New factories should not be licensed unless they fulfil these requirements.

(5.1.)

70. To prevent hardships that may result from it to small scale manufacturers they should be induced to get together, and by pooling their resources, put up properly equipped co-operative units.

(5.1.1.)

71. In the alternative, each small scale manufacturer should try to specialise in a particular type of product, after properly equipping himself for its manufacture instead of all of them trying to make a number of products without proper equipment, supervision and control as at present.

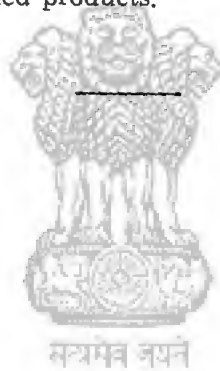
(5.1.2.)

72. In deserving cases, a time limit not exceeding one year may be given for improving their existing facilities. No latitude should be allowed while licensing firms for the manufacture of medicines for internal use specially those meant for parenteral use.

(6.2.)

73. A group of firms may be encouraged to join together and put up well-equipped testing laboratories for keeping a control on their raw materials and finished products.

(6.2.1.)



### CHAPTER III—BASIC RAW MATERIALS AND PACKING MATERIALS OF THE INDUSTRY

#### *Medicinal Plants:*

74. Government should take immediate steps to organise the cultivation of medicinal plants in a scientific manner and sponsor agencies for their proper collection, storage and marketing.

(2.3.)

75. The Madras Government should assist the Cinchona Department to establish farms for the experimental cultivation of medicinal and essential oil plants in the cinchona plantations at Anamalai and Naduvattam on a large scale as they have enough land in the plantations not suitable for cinchona but fit for the cultivation of medicinal plants.

(2.5.)

76. For carrying out experimental work on the cultivation of medicinal plants, adequate grants should be made available both by the Central and State Governments.

(2.5.)

77. Extraction of the active principles from the plants grown in these farms should be undertaken in the existing quinine factories. This will add to the economic resources of the State and help to meet the needs of the pharmaceutical industry.

(2.5.1.)

78. The Assam Government should preferably set up separate department manned with technically qualified and experienced staff to supervise and expand the cultivation of medicinal plants. The State possesses varying soil and climatic conditions from the hills to the plains and can grow most of the medicinal plants that are, at present, needed by the pharmaceutical industry in the country.

(2.6.)

79. As this work is of national importance the Central Government should actively assist the State Government by providing technical supervision and adequate grants for carrying out this work.

(2.6.1.)

80. The steps taken by the Bengal Government for the cultivation of Ipecacuanha, Rauwolfia etc., at Rongo are highly commendable. The farms especially for the cultivation of Ipecacuanha should be expanded and the extraction of emetine from it should be taken up at the quinine factory at Mungpoo. This will help the country to become independent of the imports of Ipecacuanha and emetine.

(2.7.)

81. An agency for the co-ordination of the various efforts made by the State Governments independently or under the auspices of Central Organisations like the Indian Council of Agricultural Research and the Council of Scientific and Industrial Research etc., for the cultivation of medicinal plants should be set up by the Central Government. This agency which should be fully representative of the concerned Departments of the States and the Central Government should review the work done periodically, and suggest future courses of action.

(2.8.)

82. There is tremendous scope for the cultivation and marketing of medicinal plants in various States, particularly in the Kangra Valley of the Punjab. Adequate assistance should be given by the Central Government to the States such as Punjab, West Bengal, Assam, Madras etc., for carrying out their schemes for cultivation and marketing of medicinal plants.

(2.9.)

#### *Ethyl Alcohol:*

83. There has been considerable delay on the part of the Government in giving effect to the recommendations of the Expert Committee on Excise. These recommendations should be implemented immediately to give relief to the pharmaceutical manufacturers.

(3.4.)

84. The restrictions imposed by certain state Governments, in the interests of prohibition, on the supply of alcohol to the industry such as (i) making rectified spirit a monopoly of the Government and insisting that all manufacturers should buy their requirements from Government distilleries only, at high prices; (ii) restricting production of alcohol of pharmaceutical firms which have their own distilleries, to their actual requirements; (iii) controlling the supply of molasses to such distilleries and (iv) charging heavy vend fee on the alcohol of their own manufacture used in their factory, hamper the development of the industry and should be removed.

(3.6.)

85. Unless the industry is allowed the freedom to purchase all its raw materials from the cheapest source available, it will find it difficult to take up new lines of production and progress on right lines. The State Governments should, therefore, adopt methods which will not cripple the industry and devise other means for the furtherance of prohibition.

(3.6.1.)

86. To prevent the misuse of tinctures, especially in the States where prohibition exists, the following steps are recommended:—

- (i) The production of tinctures for which no standards exist and which are not found in the British and other pharmacopœias, should be prohibited;
- (ii) The production of tinctures which are in the older editions of pharmacopœia and for which genuine demand exists, should be allowed to be produced on the basis of production and consumption before the introduction of prohibition; and

- (iii) On those tinctures which appear in the latest edition of the pharmacopoeia and are liable to misuse, the duty should be raised to the same level as on pure ethyl alcohol.

(3.7.)

87. As a result of the restrictions imposed by the Bihar Government on the export of molasses, the distilleries in Bengal are starved of their requirements of this raw material and several of them have been forced to close down. The Bengal Government, in turn, are imposing restrictions on the import of alcohol from Bihar. These measures have resulted in the scarcity of supply of alcohol to the existing pharmaceutical factories in Bengal. A better co-ordination between the two States should be brought about and full requirements of alcohol made available to the industry.

(3.8.)

#### *Methyl Alcohol:*

88. The Customs Authorities treat methyl alcohol imported by pharmaceutical manufacturers like other potable spirits and subject it to the same restrictions. A heavy duty equivalent to that charged on spirits is levied if the firms do not use it under bond, or add a denaturant to it. All this has arisen from a mistaken impression that methyl alcohol is potable and if allowed to be used freely by the industry, may interfere with the revenue obtained from potable spirits. The policy adopted, at present, should be revised and the existing restrictions removed as they come in the way of the development of the synthetic drug industry and research and testing work in scientific laboratories, where methyl alcohol forms an important item. The existing requirements are small and should be allowed to come in without any restriction.

(4.1. and 4.3.)

#### *Coaltar Products:*

89. The distillers of coaltar are not working to capacity as they are not able to get enough supplies of coaltar. Those who have to transport it over long distances are experiencing in addition serious difficulties for want of tank wagons with the Railways for the purpose. The alternative method of transporting it in drums is wasteful and seriously impairs the economy of coaltar distillation. Adequate number of tank wagons should be made available by the Railways for the transport of coaltar.

(5.2.)

90. To improve the production of coaltar products, the recovery of benzol in the coke ovens operated in the country, should be made compulsory unless the units are too small for its economical recovery.

(5.4.)

91. In order to create an incentive for coke oven plants to recover more of benzol, than that required by the petrol companies and make it available for the recovery of benzene and toluene, the excise duty levied on benzol should be removed irrespective of the purpose for which it is used.

(5.4.1.)

92. The existing practice of burning coaltar by the steel companies in their open hearth furnaces leads to a waste of an important national resource and should be stopped till such time as enough coaltar is available for purposes of distillation.

(5.4.2.)

93. The requirements of coaltar products by the pharmaceutical industry should be evaluated based on the co-ordinated development programmes of the pharmaceutical manufacturers during the next five years.

(5.7.)

94. Similar estimates of the requirements of coaltar products by the Plastic and Dyestuff Industries which are also in their early stages of development should be made and correlated with those of the pharmaceutical industry.

(5.7.1.)

95. Based on the estimates of total requirements of coaltar products of the pharmaceutical, plastic and dyestuff industries a long term programme for the production of coaltar chemicals in the country should be drawn up.

(5.7.2.)

96. The Government themselves should take up the manufacture of essential coaltar products if sufficient response from the private sector is not forthcoming.

(5.7.3.)

*Animal glands and organs:*

97. The manufacture of hormones and glandular products in the country is insignificant when compared to the demand and this is mainly due to the virtual absence of facilities for collection and storage of glands. Modern slaughter houses with facilities for proper collection and storage of glands and organs should be established to start with, in cities such as Bombay, Madras, Calcutta and Delhi.

(6.2.)

98. The collection and preservation of these glands and organs should be supervised by qualified personnel and not left to the butchers as at present.

(6.2.1.)

99. The recommendations made by the Masani Committee for the improvement of Slaughter Houses in the Bombay State, particularly with reference to the collection and storage of organs and glands of slaughtered animals should be implemented in all the slaughter houses in principal towns of the country.

(6.2.3.)

*Glass Bottles:*

100. The pharmaceutical concerns and pharmacies, while indenting their requirements of glass containers from glass manufacturers, should insist on standard specifications and decline to purchase cheap goods that do not conform to them.

(1.3.1.)

101. The manufacturers of glass containers, on their part, should produce only standard products and each manufacturer should specialise in a particular type instead of all of them trying to make all types.

(1.3.1.)

*Ampoules, Vials etc.*

102. To enable the pharmaceutical manufacturers to adopt more automatic filling and sealing, the production of machine-made tubing, and ampoules, should be expanded. The production of neutral glass tubing and its use in ampoule-making should be encouraged.

(1.4.)

*Standardisation*

103. Standards for the quality of the glass and/or alternative containers required for different purposes should be drawn up with the help of the Central Glass and Ceramic Institute and the Indian Standards Institution.

(1.5.)

104. The Standards Institution should consider suggesting different shapes of bottles to be used for dispensing medicines for internal use, and those for external use, while drawing up standards for bottles meant for packing different products.

(1.5.1.)

105. The Weights and Measures Act should be enforced strictly in all States and the practice of dispensing in bottles of lower capacity than that stated should be penalised.

(1.5.2.)

106. The standards laid down for dispensing on the lines specified by the British Standards Institutions in both Metric and Imperial Units should be adopted, in respect of containers used by dispensing chemists.

(1.5.3.)

*Cork*

107. Several species of quercus are found at different levels of Himalayas. Investigations should be carried out to see if these could serve as substitutes for cork. Simultaneously, cork-oak cultivation should be undertaken in suitable climates after the investigations in the selected areas.

(2.3.)

## CHAPTER IV—DEMAND AND PRODUCTION

### *Essentiality of Drugs*

108. A tentative list of essential drugs, whose production should be encouraged in the country has been given in Appendix No. 10. A more comprehensive list should be drawn up by an expert body comprising of the representatives of the medical profession, manufacturers and the Government and revised from time to time for inclusion or otherwise of different items to serve as a guide for the purpose.

(2.1. & 2.11.)

### *Estimates of demand and production*

109. Figures given in the Sea Borne Trade Accounts published by the Government give only quantity and value of the imports and exports under broad headings. In future, a detailed tariff classification indicating the imports and exports of all essential drugs should be included in the Imports and Customs Schedules published by the Government of India. Basic chemicals and intermediates required by the pharmaceutical industry should also be classified in detail in the above Schedules. Such information will be valuable to the industry and Government to study the extent to which the country is dependent on imports and help to plan the future development of the industry.

(3.1.)

110. In table (No. 33), approximate figures of the imports of essential drugs, their production and installed capacity where they exist and the estimates of demand have been worked out to indicate roughly the trends of consumption based on the present meagre data available. A revised table on these lines should be worked out when more accurate figures become available from the Imports and Customs Schedules. Wherever there is a gap between the estimated demand and present capacity, additional units should be encouraged to bridge the same. The Development Council, when formed, should review each item and suggest steps necessary for the purpose.

(3.2.1. & 3.2.2.)

### *Steps necessary to increase production*

111. In the case of products for which certain specified capacities for production have been claimed, and their actual production has been lagging behind, the units concerned should be asked to work and produce upto full capacity at least for a certain specified period to establish evidence of their ability to work at the capacities claimed. Once this evidence becomes available, adequate assistance should be given to the industry to operate to its full capacity and enable its products to be sold in preference to those imported.

(3.2.3.)



112. The import duty on industrial machinery and scientific equipment, not made in the country and yet required by the pharmaceutical industry for manufacturing and testing purposes, should be brought to the same level as that levied on capital equipment for other industries.

(3.2.4.)

113. Assistance should be given in the form of reduction, remission or rebate of import duties on raw materials and intermediates required by the Industry. The rebate or reduction should be so adjusted as to amount to a total incidence which would be less than the duty levied on the finished products.

(3.2.5.)

114. Imports of vitamin preparations under the O.G.L. should be stopped and put on a separate quota basis which should be gradually reduced as the indigenous production increases. Only the import of vitamins in bulk should be allowed on the O.G.L. till such time as their manufacture develops in the country.

(3.2.6.)

115. The recommendations of the Development Council for pharmaceuticals and drugs, when formed, should be taken into consideration in the formulation of the import policy in so far as it affects the development of the pharmaceutical industry.

(3.2.7.)

116. Drugs whose indigenous production is deemed to be adequate should not be allowed to be imported except to the extent of token imports considered necessary to act as an incentive for maintenance of standards and further development of the products.

(3.2.8.)

117. Consistent with meeting local demand, foreign markets should be expanded for pharmaceutical preparations by permitting their liberal exports and including them while negotiating trade agreements.

(3.2.9.)

118. The imports of unessential patent and proprietary medicines should be restricted. The Committee have been given to understand that the present practice of levying a heavy import duty on patent and proprietary medicines is having a salutary effect on reduction of their imports. It is suggested that this practice may be continued and the duty further increased as and when necessary.

(3.2.10.)

#### *Cost of production and efficiency of process employed*

119. With the exception of a few firms which may have some organised data, many of the manufacturers do not seem to maintain separate figures of cost for the production and marketing of their products. Since proper data would be useful even to the firms for assessing their own efficiency and determining their selling prices on a reasonable basis, whenever competition makes it necessary for them to do so, steps should be taken to ensure that all manufacturers maintain proper records of cost data relating to their products.

(4.1.)

120. A detailed examination of books of different firms for estimating both the cost of individual drugs and the cost of processing different formulations should be undertaken. This will enable the Government to assess the relative efficiency of different firms and also to take appropriate steps for fixing reasonable prices of commodities periodically. A separate cost accounting wing should be attached to the Development Council, when formed, for undertaking this work.

(4.2.)

121. To enable the manufacturers to assess the cost of production of pharmaceuticals and drugs from imported basic chemicals and the economics of their production, the rates of customs duly levied on the various raw materials and finished products should be indicated in the Customs Tariffs.

(4.3.)



सत्यमेव जयते

## CHAPTER V—STANDARDISATION, CONTROL OF QUALITY AND ADMINISTRATION

### *Administration of Drugs Act*

122. The Drugs Controllers both at the Centre and the States should be full-time officers and should have the following minimum qualifications:—

- (a) A Degree in Pharmaceutical Chemistry or Pharmacy or an Honours or post-graduate Degree in Chemistry;
- (b) An intimate knowledge of drug standards; and
- (c) Adequate practical experience in the manufacture and testing of drugs.

This will ensure a more efficient administration of the Drugs Act, hence statutory provisions should be made in the Drugs Rules.

(3.6.)

123. Administration of the Drugs Act requires specialised knowledge. Training should, therefore, be provided under one of the Foreign Fellowship Schemes. At least two persons should be sent out for such training every year till an adequate number of persons is available.

(3.6.1.)

### *Need for centralising the Administration*

124. In order to overcome the defects in the operation of the drug control existing at present, and to bring about a uniformity in the standard of products manufactured, the Administration of Drugs Control should be centralised by bringing control on manufacture, sale and distribution, which is at present exercised by the State Drugs Controllers, under the Drugs Controller (India). This will help to bring about a uniform enforcement of the Drugs Act and a better co-ordination in the administration of the Drugs Act and the Industries (Development and Regulation) Act.

(3.7)

125. To enable the Drugs Controller (India) to take over the additional duties indicated in the preceding paragraph and to further tighten up the control over imports which he is already exercising, the set up of the Drugs Control Administration at the Centre should be expanded on the lines indicated in Appendix No. 11. Once the Drugs Control Administration has been centralised, it will require a department of its own in the Health Ministry.

(3.7.1.)

### *Central Government Laboratories*

126. For primary testing, additional testing laboratories should be set up at the ports of entry of drugs. To ensure that importers have adequate facilities for the storage of the drugs imported by them,

additional staff to inspect their premises and take samples more frequently from their godowns should be appointed.

(3.9.)

127. With the centralisation of the Drugs Control Administration and improvement in the operation of the Drugs Control throughout the country, the work of the Central Drugs Laboratory, Calcutta, will be greatly increased. Hence steps should be taken to supplement the staff and testing facilities as and when the need arises.

(4.1.)

128. The salaries of the Laboratory Assistants in the Central Drugs Laboratory, Calcutta, who actually carry out the analysis of the products are fixed at a ridiculously low scale of Rs. 40—75 and Rs. 60—105. In view of the responsible nature of the work, it is recommended that their scales should be revised as follows:—

Graduates—Rs. 100-5-120-8-200-10/2-220.

Intermediates—Rs. 60-4-120-5-150.

Taking into account the importance of the work entrusted to them it is recommended that in future only graduates in Science should be recruited to these posts as and when vacancies arise.

(4.1.1.)

129. A uniform scale of pay of Rs. 160—450 should be given to Assistant Chemists, and Assistant Biochemists on the same basis as given to Assistant Pharmacologists and Assistant Bacteriologists. The existing discrimination among the same category of staff doing similar type of statutory work adversely affects their efficiency.

(4.1.2.)

#### *State Government Laboratories*

130. The existing laboratory facilities for testing samples of drugs are inadequate in all the States. In every State or group of small States a well-equipped independent laboratory should be set up which should not form an appendage to any of the existing Public Health, Food or Chemical Laboratories.

(4.2.2.)

#### *Manufacturers' Laboratories*

131. In addition to a scrutiny of the testing facilities maintained by manufacturing concerns, a frequent check of the records and test reports maintained by them in these laboratories should be made to see that their products are being regularly and properly tested.

(4.3.)

132. The medical profession and pharmaceutical industry should join together in setting up testing laboratories for the purpose of certifying the products made by the Industry and thus create confidence among the public in the products manufactured by them.

(4.3.2.)

133. The Government should render financial assistance by way of grants or subsidies for testing laboratories of the type proposed above. Assistance may also be sought from International Organisations like W.H.O., T.C.M., U.N.I.C.E.F., etc. The Government should recommend such requests for assistance.

(4.3.2.)

#### *Public Analytical Laboratories*

134. The confidence in the results of Public Analytical Laboratories in the country is of primary importance. The Drugs Control Authorities should keep a constant check on their activities and also verify the adequacy of equipment, staff and their technical competency.

(4.4.)

135. When approval is given by the Drugs Controller to a manufacturer to have his products tested at one of the approved laboratories, adverse reports are not sometimes field in the records. A copy of every report should be sent direct to the Drugs Controller.

(4.4.1.)

#### *Industries (Development and Regulation) Act*

136. The definition of a factory in the Industries Act as applied to the pharmaceutical industry should be amended to that given under the Factories Act, 1948, so as to bring smaller units under the purview of the Act and thus facilitate their development.

(6.2.)

137. At present, there are a common set of "Rules" under the Act for all the 42 industries included in the schedule of the Industries (Development and Regulation) Act. As the problems of the pharmaceutical industry are peculiar in some respects, a separate set of "Rules" for this industry should be prepared by modifying the existing Rules and/or incorporating new clauses wherever necessary.

(6.3.)

#### *Coordination with Drugs Act*

138. The licence under the Industries (Development and Regulation) Act should be granted subject to the factory obtaining a licence under the Drugs Act. There should be a perfect co-ordination between licensing under the Drugs Act and licensing under the Industries Act. Licences should be issued under the respective Acts only after consultation between the two concerned Departments of Government.

(6.4.)

#### *New Grouping*

139. Firms should be licensed to manufacture drugs under the Industries (Development and Regulation) Act, according to any of the two groupings given in the classification in Lists A & B of table No. 35.

(6.5.)

### *Development Council for Pharmaceuticals and Drugs*

140. To ensure future development of the pharmaceutical industry on the lines of our recommendations, immediate steps should be taken by Government to constitute a Development Council for Pharmaceuticals and Drugs. This Council should be under the Ministry of Commerce and Industry and it should include:—

- (1) The Industrial Adviser (Chemicals);
- (2) The Drugs Controller (India);
- (3) Representatives of the Industry;
- (4) Representatives of consumers who in this specific industry are medical men; and
- (5) Representatives of the pharmaceutical trade viz., distributors, wholesale and retail pharmacists.

Adequate functions should be assigned to the Council for implementing the recommendations of the Committee. For carrying out these functions sufficient technical and secretarial assistance should be given.

(6.6.)

### *Amendments to Drugs Act and the Rules thereunder*

141. The term "manufacture" should be defined for the purposes of this Act as under:—

"'Manufacture' in relation to any drug includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale and distribution but does not include the compounding or dispensing or the packing of any drug in the ordinary course of retail business."

(7.1.1.)

142. The term 'Drug' should be defined on the lines of the Federal Food Drugs and Cosmetics Act of the U.S.A. This definition is reproduced below:—

"The term 'drug' means (1) an article recognised in the official United States Pharmacopoeia or Official National Formulary or any supplement to any of them; (ii) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (iii) Articles (other than food) intended to affect the structure or any function of the body of man or other animals."

Adoption of such a clause will bring disinfectants, insecticides and contraceptives and the standards for such disinfectants, insecticides and contraceptives as would be prescribed, under the purview of the Drugs Act.

(7.1.2.)

143. At present, there is provision for the marketing of proprietaries with secret formulae after registration in the Central Drugs Laboratory. This provision should be withdrawn and no patent or proprietary preparation with secret formulae should be allowed to be marketed. Any product to be marketed must have its composition and method of usage published on its label.

(7.1.3.)

144. Offences under the Drugs Act for trading in spurious and substandard drugs should be made cognisable. A deterrent punishment with adequate fine and a compulsory period of rigorous imprisonment should be given.

(7.1.4.)

145. Giving of adequate publicity to the offender's name and address should be made compulsory.

(7.1.5.)

146. The trading Licence of such an offender should be cancelled and it should be made impossible for him to restart the trade either in his own name or in partnership with others.

(7.1.6.)

147. In cases, where a licence has been suspended for the contravention of the clauses dealing with trading in spurious and substandard drugs, irrespective of the particular licence to which the offence relates, all other licences should also be suspended and the establishment forced to remain closed.

(7.1.7.)

148. Suspensions should ordinarily be not given in case of technical offences like non-maintenance of records, etc., which should normally be punished by a fine unless offences have been recurring often.

(7.1.8.)

149. It has to be pointed out that at present, the possession of spurious drugs is not an offence, until the sale of such a drug is effected. The possession of spurious drugs should also be made an offence under the Drugs Act.

(7.1.9.)

150. The possession of any die, plate or other instrument for the purpose of counterfeiting any label or wrapper of a drug, or the possession of a trade mark or proprietary mark for the purpose of falsely denoting that any drug is the manufacture or merchandise of a particular person or firm, should be made an offence. The punishment should be either imprisonment extending upto a period of three years or a heavy fine or both.

(7.1.10.)

151. The provision whereby an Inspector, under the Drugs Act, has to take the permission of a District Magistrate or the Chief Presidency Magistrate for search or seizure of adulterated or misbranded drugs should be deleted.

(7.1.11.)

152. To safeguard the interests of the public against unsuitable and harmful formulations, Sections 12(m) and 33(k) of the Drugs Act should be made applicable to all formulations of drugs and medicines sold in the country.

(7.1.12.)

153. Minimum requirements of premises, sanitary conditions, equipment and qualified personnel for the manufacture of different products should be specified in the Rules under the Drugs Act.

(7.1.13.)

154. No licence for the manufacture of pharmaceuticals should be given unless the conditions regarding minimum requirements are fulfilled. Licences for the existing factories that do not fulfil these conditions should be revoked.

(7.1.14.)

#### *Revision of licence fees*

155. The Rules under the Drugs Act prescribing licence fees for importing, stocking, exhibiting, selling and manufacturing of drugs and medicines should be revised and the fees increased as indicated below in order to prevent unhealthy competition in the trade which has been flooded with unqualified people. While making it clear that the fees should not be viewed as a source of revenue, Drugs Control being a social legislation, it is considered that the revenue from an increase in the fees will meet part of the expenditure that has to be incurred for an efficient administration of the Drugs Act as suggested.

The existing licence fees are:

*Form 10.*—Licence to import biological and other special products specified in Schedule C and C1 to the Drugs Rules—Rs. 10 for two years.

*Form 20.*—Licence to sell, stock and exhibit for sale and distribute drugs other than biological and special products specified in Schedule C—Rs. 5 for two years.

*Form 21.*—Licence to sell, stock and exhibit for sale and distribute biological and special products specified in Schedule C—Rs. 5 for two years.

*Form 25.*—Licence to manufacture drugs other than biological and special products in Schedule C and C1—Rs. 20 for two years.

*Form 28.*—Licence to manufacture biological and other special products specified in Schedule C and C1—Rs. 20 for two years and an inspection fee of Rs. 100 at the time of application for licence.

#### *The revised licence fees should be*

*Form 10.*—The fee for an import licence for the import of any biological or other special products specified in Schedule C and C1 should be Rs. 200 for two years with an endorsement fee of Rs. 100 per endorsement.

A licence fee should be imposed for the import of products not specified in Schedule C and C1 at the rate of Rs. 50 for two years for each manufacturer abroad.



**Forms 20 and 21.**—Licence for stock and sale of drugs should be in two categories and no trader should be allowed to trade both as a wholesaler and retailer *in the same premises*. Separate licences should be obtained if the same person sets up business both as a wholesaler or a retailer.

In the case of wholesalers, there should be two categories of licences:—

- (a) *A distributor for limited number of manufacturers and importers.*

A fee of Rs. 500 for 2 years should be charged for one or more groups of manufacturers provided he does not represent more than 10 manufacturers. For every additional manufacturer whom he represents, a fee of Rs. 100 for 2 years should be charged.

- (b) *A general wholesaler who deals in all types of drugs and medicines from all importers and manufacturers.*

A fee of Rs. 1,000 for 2 years should be charged.

The above scale of fee for distributors should not vary, wherever they are situated within the territory in which they operate, but for wholesalers who are not situated in big towns like Bombay, Calcutta, Delhi and Madras, the fee should be as follows:—

Cities with a population of	Fees for 2 years
	Rs.
5,000 and under . . . . .	5
5,000 to 50,000 . . . . .	20
50,000 to 1,00,000 . . . . .	50
1,00,000 to 5,00,000 . . . . .	100
5,00,000 and above . . . . .	200

In cities of Bombay, Calcutta, Delhi and Madras the fee for a retail licence in Forms 20 and 21 should be Rs. 500 for 2 years for each. For other cities, the same scale of fee mentioned above for wholesalers should be charged.

**Form 25.**—A manufacturing licence for drugs other than biological and special products should be Rs. 1,000 for 2 years initially and for every new product endorsed, it should be increased by Rs. 50 subject to a maximum of Rs. 2,000 for 2 years.

**Form 28.**—Licence fee for the manufacture of biological and special products should be a minimum of Rs. 2,000 with an endorsement fee of Rs. 50 per item subject to a maximum of Rs. 4,000 for 2 years.

The inspection fee should be Rs. 250 for the first inspection before the grant of a licence and Rs. 150 for every subsequent inspection at the time of renewal.

The inspection of a factory for the manufacture of products specified in Schedule C and C1 of the Drugs Rules should be conducted by a panel of experts at least one of whom shall be a person suitably qualified for such inspection.

The licence issued for manufacture will include the licence for sale by way of wholesale transactions from the factory. If, however, the factory has a separate place where manufactured goods are stocked and sold in the same town, such premises should be licensed as a wholesale distributor. Normally, no manufacturer should be allowed to act as a distributor also. Established traders should be encouraged to act as distributors.

(7.1.15.)

156. In as much as the country at present possesses more than ample processing capacity, the system of "loan licensing", whereby quite a number of pharmaceutical firms, having no factory of their own, market their products by getting them manufactured in any of the well-equipped and well-staffed factories, could be adopted for some time at least for utilising the surplus capacity. A licence fee of Rs. 400 for two years for such loan licences should be imposed and permission for manufacturing new products should be endorsed on such licence, each endorsement being charged Rs. 20 for two years

(7.1.16.)

#### *Licensing of Crude drug dealers*

157. For the proper development of the Pharmaceutical Industry, it is necessary to see that the quality of the crude drugs used as raw materials should be ensured. At present, these are handled by people who are not qualified by education or training to do so. In order to improve the quality of the crude drugs available in the market, dealers of such drugs and their premises should be licensed and limited to those who are in a position to guarantee their quality to the manufacturers, and exporters.

(7.1.17.)

158. It should be made compulsory that every licensed dealer in such drugs should give a warranty about their active constituents.

(7.1.18.)

159. Manufacturers who obtain their crude drugs requirements directly should be licensed as dealers in crude drugs.

(7.1.19.)

160. A licence fee of Rs. 100 for 2 years for such registered dealers should be imposed and provision for this made in the Drugs Rules.

(7.1.20.)

#### *Chemical name vis-a-vis proprietary name*

161. Rule 109(1) (a) which reads as follows, is at present applicable to Schedule C drugs. This Rule should be made applicable to all drugs and rigidly enforced. It should apply, in addition to the labels on the containers, to advertisements in Medical, Scientific and Trade Journals and the literature distributed to the medical profession and chemists and druggists.

"Rule 109(1) (a): *Labelling*: (1) Every phial, ampoule or other container of a substance specified in Schedule C shall bear a label  
41 M of C & I

on which is printed or written in indelible ink the following particulars and such further particulars, if any, as are specified in Schedule

- (a) The proper name of the substance in letters not less conspicuous than those in which the proprietary name, if any, is printed or written and following immediately after or under such proprietary name."

(7.1.21.)

162. In the case of combinations the names of the main ingredients should be displayed in letters of readable size on the labels of the containers and in the advertisements and in medical literature.

(7.1.22.)

*Staff for inspection and testing*

163. Sufficient number of well-qualified and properly paid Inspectors should be appointed so that the premises of drug manufacturers, distributors and traders may be more frequently inspected and samples drawn and tested.

(7.1.23.)

164. The scales of pay of Inspectors should be uniform throughout the country and should start with a minimum of Rs. 275 per mensem. One Inspector should be appointed for not more than 200 selling premises or for not more than 100 manufacturing premises, so that every shop or factory could adequately be inspected.

(7.1.24.)

165. The Committee have observed that sufficient staff is not provided in many Government testing Laboratories. These should, therefore, be adequately staffed and the Government Analysts appointed should possess special qualifications in Chemistry in addition to sufficient experience in the modern technique of drug analysis.

(7.1.25.)

*Problem of re-use of old containers*

166. The problem of the re-use of old containers has assumed serious proportions. Wide publicity for this is required and the co-operation of the public, the medical profession and chemists and druggists should be sought for prompt destruction of such containers and thus prevent them from falling into the hands of unsocial elements. Documentary films, cinema slides and posters should be used for giving wide publicity to check this malpractice.

(7.1.26.)

167. Chemists and Druggists should organise themselves and advertise in the leading professional and Trade Journals and newspapers that quality drugs can be had from their Member-Firms, who should be made to display, in a prominent place of their shop, a badge distributed by the Association. The advertisements should state that the prices of drugs sold by such firms are the fair prices. Such propaganda will not only induce all the chemists to join the Association but also infuse into the minds of the public a sense of confidence in the quality of drugs sold by such dealers.

(7.1.27.)

168. The use of pilfer-proof closures should be strongly encouraged and for certain drugs, their use with a seal or stamp should be made obligatory.

(7.1.28.)

## CHAPTER NO. VI—RESEARCH WORK

169. Evaluation of drugs require team-work by several groups of scientists. It should be actively encouraged as and when facilities for such team-work become available with the setting up of more Research Laboratories.

(2.5.2.)

170. Government should encourage investigations for the improvement of economic plants that are now being grown in the country for obtaining better yields of their active principles.

(2.5.4.)

171. To prevent annihilation and maintain a regular supply of certain medicinal plants like Rauwolfia, their indiscriminate exploitation should be stopped.

(2.5.5.)

172. Experimental farms should be set up to determine the best seasons for cultivation and collection of medicinal plants. Based on this information, large scale farms should be established to ensure regular supply.

(2.5.6.)

173. Research in pharmacology in this country is lagging behind chemical research and this is one of the reasons which prevents the development of chemical research in the field of drug Industry. This should be overcome by providing more adequate personnel, equipment and finances for research work in medical colleges.

(2.6.1.)

174. In order to provide the required number of research workers, it is necessary to train large number of Chemists and Biologists in pharmacology in addition to medical men.

(2.6.3.)

175. To overcome the handicap for lack of adequate equipment and funds for undertaking researches in pharmacology by the medical colleges, the Committee recommend that these institutions should be given substantial grants by the Central and State Organisations sponsoring research to enable them to carry out investigations in this important field. The progress made by these institutions should be closely watched by the sponsoring research organisations and similar work carried out in other institutions should be properly co-ordinated.

(2.6.3.)

176. It should be made incumbent on the manufacturers to spend a certain percentage of their profits on research. The financing of research in the University Laboratories and other research institutions by commercial concerns should be encouraged as it is advantageous to both. Research in such institutions should, as far as possible, be original.

(2.7.5.)

177. Foreign firms which have established factories in India and utilise the profits derived in India for research in their own countries should be asked to employ Indians in increasing numbers and give them training in research institutions run by them in their countries. They should also establish in India research laboratories as early as possible and spend a portion of profits on research in these laboratories or contribute financially towards research development in the country.

(2.7.6.)

178. Any contribution made by pharmaceutical firms for research to Universities and other exclusive research institutions should be allowed a rebate of income-tax.

(2.7.6.)

179. Properly designed pilot plants should be set up for investigating the economics of production of drugs and to collect sufficient chemical and chemical engineering data to be able to put up large scale plants for commercial production.

(2.7.9.)

180. Government should finance liberally research in pharmaceuticals and drugs in Universities, Medical Colleges and other institutions and expand the activities in this field of the institutions directly under their control.

(3.1.)

181. The Development work in drugs which involves co-ordinated effort of a number of research departments should be entrusted to Government institutions like the Central Drugs Research Institute, Lucknow. These institutions should concentrate more on such type of work. Research work of a fundamental nature should be entrusted to University laboratories and other research laboratories. In the case of laboratories of commercial firms, a similar distribution of work should be aimed at depending on the facilities that exist.

(3.2.)

182. Special emphasis should be laid on research: (i) on vegetable drugs of reputed value; (ii) for the discovery of new therapeutic agents for treatment of diseases common in India, and (iii) for investigating new antibiotics from Indian sources.

(3.3.)

183. Research Institutes in the country should keep a careful watch about the effects of the new remedies that are being introduced into medical practice in rapid succession and make periodical reports. The country is now mainly dependent on foreign countries for such information. A panel of Experts should be appointed to report periodically about these drugs and their reports published.

(3.3.1 & 3.4)

184. Clinical and experimental trials for investigating the therapeutical properties of new compounds synthesised in the country should be undertaken by the Army hospitals and hospitals attached to teaching institutions. The Panel of Experts proposed above (Recommendation No. 183) should also report periodically about such trials.

(3.4.1.)

## CHAPTER VII—DISTRIBUTION AND ADVERTISEMENT.

### *Distribution*

185. Drugs and medicines should not be allowed to be sold in Grocers' shops, Restaurants and by General Merchants in cities and large towns.

(3.4)

186. A system of fair trade prices should be established and the existing price cutting which leads to many malpractices including the sale of spurious and adulterated drugs should be stopped. The consumers' price of all drugs and medicines should be fixed by an organisation representing the Government and Trade. A catalogue showing such consumer's prices should be published and made available for inspection at every Chemist's shop.

(3.6)

187. Goods should be sold only at the prices so fixed and any deviation should entail the cancellation of the licence.

(3.6.1)

188. While arriving at the consumer's price, the discount to the trade should be fixed at a reasonable figure of say 25 per cent. of the price at which the goods are sold to the trade *viz.*, the retailer or wholesaler, with an extra  $1\frac{1}{2}$  to 2 per cent. to cover packing, etc.

(3.7.1)

189. The importer or manufacturer should sell only in certain specified lots and when a trader wants a quantity less than this specified lot, he should obtain it from the general wholesaler.

(3.7.2)

190. The general wholesaler should sell at a price which gives him a profit of 10% and pass on the balance to the retailer.

(3.7.3)

191. Certain manufacturers and importers supply drugs and pharmaceuticals direct to the hospitals in consumer packs at prices lower by as much as 15 per cent. than the prices to the trade. Such supplies may have a way of finding themselves into the open market and disrupt the normal trade. Concessional rates to hospitals should be given for special hospital packs only and not for supplies made in the ordinary packs. As far as possible, even supplies to the hospitals should be made through recognised trade channels.

(3.7.4)

192. A high priority should be given to the transport of pharmaceutical products. Consignments of medicines should be provided with special 'rush labels' so that even small packages could be moved at a faster rate.

(3.8)

193. Refrigeration facilities should be provided both in the railway wagons and godowns for the movement and storage of heat sensitive medicinal products.

(3.9)

194. At present, the tariff rates for drugs and medicines have been fixed at the same level as those for luxury articles. These rates should be reduced to conform to the lower parcel rates.

(3.10)

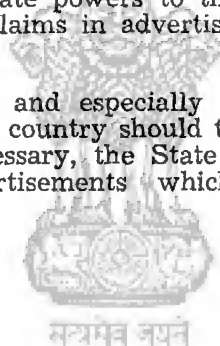
*Advertisement:*

195. Whilst stringent labelling provisions are laid down in the Drugs Rules, these unfortunately do not apply to advertisements in the lay-press or medical journals or to literature supplied to doctors. This is a serious lacuna and should be rectified if the blatant and even false claims often made by the unscrupulous manufacturers are to be stopped. The Advertisement Bill which was passed by the Council of States and adopted recently by the House of the People, will give adequate powers to the authorities to deal with false and unjustifiable claims in advertisements.

(4.4 & 4.4.1)

196. The newspapers and especially publishers of journals in Indian languages in this country should themselves set up a code of advertising and, if necessary, the State should step in to put an end to suggestive advertisements which exploit the credulous public.

(4.4.2)



## CHAPTER VIII—MEDICAL PROFESSION AND THE PHARMACEUTICAL INDUSTRY

### *Use of compounded preparations*

197. The Expert body proposed in Chapter IV for determining the essentiality of drugs should prepare a list of standard combinations which are considered essential and which should be allowed to be manufactured or imported.

(5.3)

198. A National Formulary when drawn up will prevent unnecessary and useless preparations being put in the market. The Committee, however, feel that the time is not yet ripe for drawing up such a Formulary. Its preparation should be held over till the Indian Pharmacopoeia is published. An attempt has been made in this respect by the States of Madras and Bombay which have published a "General Hospital Formulary" giving various standard prescriptions and drugs used in all Government and local fund Medical Institutions of the State. Similar procedure should be adopted by other States for the use of their various institutions till a National Formulary is drawn up.

(5.4)

## CHAPTER IX—TECHNICAL TRAINING FOR THE PROFESSION OF PHARMACY

### *Status of the Profession*

199. The profession of pharmacy should be given a recognised place in society. This could be attained by improving the standards of education in pharmacy and by regulating the profession.

(1.1)

### *Training in Pharmacy*

200. State Governments and Universities which have started courses of study in pharmacy for entering the profession should review the available facilities for training and bring them in conformity with the Education Regulations prescribed by the Pharmacy Council of India.

(4.1)

201. The Pharmacy Council of India which, at present, lays down the minimum registrable qualifications for Pharmacists should also lay down minimum standards for Degree Courses in Pharmacy. Such Degree Courses, at present, adopted by various Universities should conform to the minimum standards laid down by the Pharmacy Council of India.

(5.1)



202. To enable students to migrate from one University to another at an appropriate stage, there should be a uniform minimum standard of education in the different Universities. There should be provision for post-graduate training in different branches of pharmacy in the various Universities.

(5.2.1)

### *Pharmacy Act*

203. Pharmacy Act should be made operative uniformly throughout the country by extending it to all the States of the Indian Union.

(6.1.1.)

204. The Pharmacy Council should be empowered to draw up a code of ethics for the profession of pharmacists which should be enforced rigorously.

(6.1.2.)

205. The standards of education prescribed by the Pharmacy Council should not be relaxed.

(6.1.3.)

206. There are no provisions in the existing legislations for controlling the practice of pharmacy. A list of minimum equipment and reference books necessary for the efficient running of a Pharmacy should be drawn up and enforced. A tentative list drawn up by the Committee is given in Appendix No. 14.

(6.1.4.)

### *Dispensing of drugs.*

207. Dispensing of drugs should ordinarily be done by Pharmacists. A person should be allowed to enrol either as a pharmacist or as a medical practitioner but not both. Medical practitioners may, however, be allowed to dispense drugs to their own patients. The medical practitioners should, as far as possible, employ qualified persons to do the dispensing work.

(6.1.5.)

208. The question of requirements for a general practitioner in maintaining his dispensary in the proper way, should be examined by the State and Central Medical Councils. It should be considered necessary for them to maintain minimum equipment and requisite storage arrangements and adequate maintenance of proper records on the lines of those provided under the Drugs Rules.

(6.1.6.)

209. The medical and pharmaceutical professions should organise themselves in such a manner as to foster a spirit of amity and mutual co-operation by inviting the representatives of one profession for the conventions and meetings of the other profession.

(6.1.7.)

210. There should be at least one model institution in each State for providing courses of study in pharmacy. A Central Institute of Pharmacy should be established under the auspices of the Central Government.

(6.1.8.)

*Employment of Pharmacists*

211. The scales of pay that are applicable to pharmacists in the Centre and States should be upgraded wherever they are low. A minimum scale of pay of Rs. 80—5—120—EB—8—200—10/2—220 should be given to those pharmacists who are Matriculates and are eligible for registration under the Pharmacy Act. To provide necessary incentive for work, a selection grade carrying a scale of pay of Rs. 160—10—300—EB—15—450 should be created.

(6.1.9.)

212. Chief Pharmacists for all large hospitals should be graduates in pharmacy.

(6.1.10.)



## CONCLUSION

In conclusion, we wish to reiterate our firm conviction, that the future of the industry depends on the efforts made by the manufacturers to produce pharmaceuticals and drugs starting from basic chemicals within the country itself. To undertake such manufacture, considerable technical knowledge, special plant and equipment, laboratory control and facilities for research are necessary. It will be the duty of the Government to (a) extend all possible help to manufacturing organisations to provide themselves with these facilities, so that they develop on a regulated and planned basis; (b) co-ordinate the interests of manufacturers, traders and consumers as discussed in detail in this report; and (c) see that the highest ethical standards are maintained in this industry and trade. The recommendations that we have made in the report, we feel, when implemented will help largely in achieving these objects. We have specially kept in view the interests of the consumers, who are vitally concerned in this matter.

We wish to sound a note of caution, however, that unless these recommendations are implemented *in toto*, the desired results may not be achieved. Sometimes the partial implementation of recommendations may even lead to difficulties. For instance, an enhancement in the licence fees of traders without ensuring them a minimum return by fixing fair trade prices and preventing under-selling may only worsen the position.

We see for the industry a great future, when it develops on a planned basis; and in view of its vital nature we recommend that no effort should be spared to see that it does develop on right lines.

## ACKNOWLEDGEMENTS

At the outset we wish to place on record our gratitude to the Hon'ble Shri T. T. Krishnamachari, Minister for Commerce and Industry, Government of India, for the personal interest evinced by him in the working of this Committee and the encouragement and kindness we have received from him throughout. It was as a result of his foresight that this enquiry by the Committee was undertaken. We also offer our sincere thanks to the Hon'ble Rajkumari Amrit Kaur, the Minister for Health, Government of India for her valuable co-operation and help.

We gratefully acknowledge the assistance that we have derived from the reports published by Government, scientific literature and other references, on which we have drawn freely. In order to avoid repeated references to the sources in the body of the report, we have given at the end of the report a bibliography which indicates the publications, that we have consulted and used. Any omission that may have inadvertently occurred in the bibliography is regretted. We thank the Government of India and the State Governments for all the help rendered to us during our visits to different parts of the country to study the position of the industry and trade, and for the courtesy and hospitality they extended to us during these visits. We acknowledge with thanks the valuable assistance and co-operation we have received from the manufacturers, traders, medi-

cal men, and their respective associations. They also submitted to us detailed memoranda on the Terms of Reference of the Committee.

We wish to place on record our high appreciation of the work of Dr. B. Shah, our energetic and versatile Secretary, who collected and placed before the Committee valuable information and prepared drafts which were of great assistance in presenting this report. His previous experience of having worked as the Secretary of an important Committee set up by the Government of India "The Salt Experts Committee" was very helpful and, we are, thankful to the Ministry of Production for sparing his services. We also thank Shri K. Vyasulu, who worked as the Secretary of the Committee at the earlier stages and did the preliminary work for the enquiry of the Committee.

We place on record our appreciation of the efficient services rendered by the staff of the Committee, particularly Messrs. S. D. Sharma, C. B. Tawakley, Amar Das, and M. L. Katial who put in their best efforts to get the work completed as expeditiously as possible. They are to be specially complimented as the work undertaken was highly technical and unfamiliar to them.

(Sd.) S. L. BHATIA (Major General)—*Chairman.*

(Sd.) K. VASUDEVA RAO—*Member.*

(Sd.) B. B. YODH—*Member.*

(Sd.) J. C. GHOSH—*Member.*

(Sd.) T. N. BANERJI—*Member.*

(Sd.) R. C. SHAH—*Member.*

(Sd.) T. R. SESHADRI—*Member.*

(Sd.) H. R. NANJI—*Member.*

(Sd.) K. R. CHANDRAN—*Member.*

(Sd.) P. M. NABAR—*Member.*

(Sd.) A. NAGARAJA RAO—*Member.*

(Sd.) B. SHAH—*Secretary.*

*Bangalore, the 2nd June, 1954.*



**APPENDICES  
AND  
BIBLIOGRAPHY**



सत्यमेव जयते



सत्यमेव जयते

## APPENDIX NO. I

THE RECORD OF SPEECHES DELIVERED BY THE HON'BLE MINISTER FOR COMMERCE & INDUSTRY AND THE HON'BLE MINISTER FOR HEALTH AT THE INAUGURAL MEETING OF THE PHARMACEUTICAL ENQUIRY COMMITTEE HELD IN DELHI ON THE 12TH MARCH, 1953.

*Welcome speech by Shri T. T. Krishnamachari:*

RAJKUMARI AMRIT KAUR AND FRIENDS,

I welcome the Members of the Pharmaceutical Enquiry Committee, and in doing so I would express my gratitude to all those who have agreed to serve on this Committee. I think we are fortunate in having been able to secure the services of Major General Bhatia as Chairman of the Committee. I know, he and the other gentlemen who have agreed to serve on the Committee are professional people, very busy people, and when they agreed to spare time for this work they are making a great sacrifice.

The object of the enquiry, comparatively unimportant as it may sound to the ordinary lay-man, is, from the point of view of Government, to cover a vital portion of our life. I would like to leave it to Rajkumari Amrit Kaur to deal with the importance of the industry. You know that a large sum of money is being spent by the common man on drugs. Our import figures show progressively an increase—Rs. 8 crores three years ago, Rs. 10 crores two years ago and about Rs. 15.5 crores last year—in the matter of medicines only. We have really not made any progress so far in the manufacture of drugs and medicines in this country. We do remember the methods of Acharya P. C. Ray, who worked with a zeal. Only men of his eminence can work like that. He laid the foundations of the pharmaceutical industry in Bengal. Unfortunately—I am not saying this in any spirit of criticism—we have gone away from the proper standards and are preparing patent medicines, toilet goods etc.—Chyavanaprash and things of that sort which do not appeal to the scientist. It is certainly very offensive to contemplate this retrogression in the development of the Indian Pharmaceutical Industry which we have to face. I think most of you know the attempts which Government has been making in order to put the drugs and medicines trade on a sound footing. Our first attempt, I think, was some time in 1932, in the foreign regime, when we had a Drugs Enquiry Committee. The report of the Committee lay in the archives of the Government for a long time until my colleague Rajkumari Amrit Kaur took over the portfolio. She got a move on and we have got some kind of a Drug Control today. We have a long way yet to go, even to reach some kind of an ordinary control. At the present moment our laboratories are certainly doing useful work but they are not perhaps very effective—even the Government's own institutions—I am not saying this in a spirit of criticism, but pardon me, if as a layman I transmit to you a remark that I have heard some time



back that the vaccines manufactured in the King's Institute, Guindy, are now almost on the point of being sterile. It is not just simple criticism of our endeavours, but we ourselves know it. It is a good starting point for us to realise that we are imperfect.

On the question of the cost of drugs and medicines, we know we are a poor country. We cannot afford to pay high prices. I remember some years back I was sitting in the consulting room of one of my medical friends. One of the medical propagandists came to him showing samples and dumping literature on his head. He asked, what were the prices. The prices were fantastic. Do you know the reply my friend gave? He said "My patients are lower middle class people. They cannot afford these medicines. They have not saved enough for it. What is the use in asking me to prescribe medicines which are so costly?" But medicines are one thing on which any one, even the lower middle class man, spends a large amount of money, because life has to be saved. This is the spirit even of the lower middle class men. There has been phenomenal increase in the prices of these things after the war. This makes members of the Government like myself feel that this country cannot be exploited any further. I happened to make a casual reference to these high prices of medicines some months back. I then said we should have an enquiry into this. The effect of my statement was that there was a drop in the prices.

I find that there are many firms in the country who merely pack foreign medicines imported in bulk and sell them. Of course, even that has done some good. But I cannot for the life of me imagine how it is that ordinary drugs cost Rs. 6 or 8 rupees a small bottle. Somebody must be making money. I realise that the pharmacist has got to be paid a remuneration because he has to stock drugs and take the chance of the drugs becoming out of date in the bottle. But it is not the pharmacist whom I am complaining against. I am complaining of the manufacturer in India who allows free exploitation. The remedy perhaps is—it is a matter vital to the life of the people—nationalisation of the industry. You do not mind, friends, my being a little reminiscent. Before I became a Minister I was a socialist by conviction. I used to say "Let the free Government take over all the industries; it will do a lot of good to the country." But I came to know of the nature of the problem only when I became a Minister. Even on the question of the manipulation of the Import Control, I find that the advice that I get is inadequate. Often the advice given did not show full knowledge of the facts. I realise that we people in Government, politicians or Government servants, have little scientific background. It reminds of a story, which, at least those of you here, who are from Madras, have probably heard. A boy was asked "How many are the Pancha Pandavas?" His answer was:—They are like the legs of a cot, three in number, showed two fingers, wrote one, and wiped it out. I have found from experience that Government cannot without detriment to efficiency, assume the responsibility for nationalisation of industries. I have now therefore got cured partly of this craze for nationalisation.

I am asking you to tackle a problem which is immense. I am confident that you will undertake the task, and carry it out successfully despite the difficulties.

One of our problems of the industry is the increasing number of packing firms. Most of the drugs are not being imported now in original packing. They are imported in bulk quantities and packing is done by these firms. Of course it may be beneficial in a way. In the case of medicinal drugs instead of importing them in bulk quantities, if you obtain them in original packing in smaller required units, it may cost a little more. Some kinds of drugs can even be imported in concentrated form and they can be diluted here, but I cannot say that this applies to all medicines. The most dangerous thing associated with certain drugs is the time limit indicated by the manufacturers within which alone the drug retains its potency. In the case of such drugs, if repacking is done here, some date is given on the packages and often times it has been proved that the stuff has lost its effective qualities much before the date indicated. Take, for instance, penicillin. I do not think it would be a wrong thing if Government bans the repacking of penicillin by anybody here. When the drug is manufactured, the manufacturers naturally fix a date. But I do not know if the same date is also fixed by the firms who imported the drug in bulk quantities and repack them. But I have known people who used such repacked stuff and spoke ill of the Government and of their incompetence. Recently a Government Factory Manager saw a rule somewhere of the Federal Bureau of Health which said that the date for a certain imported bulk of penicillin could be extended. That rule was reproduced forthwith as a circular. The person in charge did not even realise that there should be some examination about the matter. After all if the dates are to be extended, it could be done only after tests are made and not in the manner in which it has been done. What therefore happens is that drugs whose utility value is time barred are still sold to the public and no wonder such drugs instead of doing any good, kill the patient sometimes. We are thus creating a sense of fear in the minds of the public when they go to the market to purchase these drugs. I am inclined to trace this fear to our allowing people to import all kinds of medicines in bulk quantities and then repack them here. That is one of the things to which I wanted to draw your attention today, but I may be wrong. After all I am a layman and I am only trying to give you my point of view on the subject.

The other aspect of this is the manufacture of ethical preparations. Even supposing that the production of these is given more and more to the Governmental sphere and the government start manufacturing some of these what is the way to meet the huge demand throughout the country? The establishment of national health services in the country would require something being done in regard to this sector. There is considerable trade outside ethical preparations, which are also considered essential drugs. You cannot prevent people from buying specifics with undisclosed composition. The advertisements on these drugs indicate more than one disease which can be cured by them within a short time. Whether they are really effective or not is another question, but human psychology being what it is today, people prefer to try these drugs before they go to a doctor and you cannot simply prevent people from seeking remedies of the type provided by these drugs. These drugs have come to stay as primary medicines and I myself have used them a number

41 M of C & I

of times. There is nothing secret about these medicines; we know what their components are and several manufacturers are making these preparations. But I feel that an investigation into such preparations is necessary and that standards should be prescribed.

The problem before you is extremely complicated, wide and bewildering and I do not think I deserve your thanks for having asked you to become members of this Committee. From the side of Government it is going to be a joint endeavour of all the concerned Ministries, *viz.*, the Ministry of Production, the Ministry of Health and my own Ministry. Every year we are spending so much of our foreign exchange on the import of medicines from abroad and yet the country's needs are not fully met. I do not have the patience to let things go on in this manner any further. I know by reducing our imports to the minimum and producing a large variety of medicines in our own country, we will be depriving many middle men of their livelihood. Many big firms have in the past acted as agents to foreign drug manufacturing concerns and they made quite a lot of money out of this business. Even now they have an important role to play in the promotion of the drug industry of this country.

We have got to carry out many researches in this field and we have yet to produce a number of new drugs. Let us also realise that we have got the necessary resources both in men and raw materials to the setting up of a fine industry in India. I think that I have been able to bring forth to you some of my own views in so far as they relate to your problem. From many Indian Chemical manufacturing associations and Pharmaceutical Associations we have received complaints that we have not given them representation. While this is true, I feel that they are people who only know the trade. We want the scientists to come and help us in this enquiry. It may be the scientists do not know how these medicines are packed, how prices are added up. I am sure you do not know it and it is not necessary for you to know it. So we want professional people who are only concerned with the public to express an opinion on the state of our industry and suggest ways of running it on sound lines.

Now before I ask my colleague, Rajkumari Amrit Kaur to inaugurate this Committee, may I tell you that this is not something that I have started. This is a common trouble and she has as much concern about it, in fact she is more concerned about it. All of us are anxious that we should lead our drug industry on the right lines, and that the common man should be benefitted by whatever efforts we do to improve this industry. We are far behind the western nations in this respect and it is time that something substantial is done. By inaugurating this Committee, Rajkumari will set the ball rolling and I hope the work of the Committee will be finished as quickly as possible. May I therefore on behalf of my Ministry and on behalf of the Committee request Rajkumari Amrit Kaur to inaugurate the Pharmaceutical Enquiry Committee.

*Inaugural Address of Shrimati Rajkumari Amrit Kaur*

I am happy to be present here to inaugurate the Committee on Pharmaceutical industry—an industry so vital for the medical care of the population. From the terms of reference you will see that this Committee is to enquire into the various aspects concerning the pharmaceutical industry, the object being to recommend steps to Government to put the industry on a sound footing and to help its development in all respects. Indeed, the recent passing of the Industries (Development and Regulation) Act and the inclusion of pharmaceuticals as one of the subjects covered by it necessitates a preliminary enquiry like the one envisaged so that its efforts by way of fact-finding will help to guide us in our plans for future development.

The question of making the supply of drugs and medicines available to the needy has all along engaged the attention of the Government of India and the Committee now appointed will naturally go into the question of the present structure of the trade so far as this aspect is concerned. While going into the overall structure I have no doubt that in addition to the interests of the traders and manufacturers, you will keep uppermost in your minds the interests of the consumers. In a country like India where the purchasing power of the people is limited, it should be our endeavour to see that they get the necessities of life at a reasonable cost.

Next to food, medicines are one of the most essential commodities for the maintenance of standards of health of the people. Our aim should, therefore, be to ensure that the medical requisites available in the country are not only of standard quality but sold at prices which will be within the reach of the masses. The ideal conditions necessary for the creation of a national health service are still a dream but we have to work from today to build for its eventual realisation. In this structure, drugs must play their part and in our present situation, we have to try to make the burden of cost of medicines lighter than is the case at present. Efforts on governmental level alone will not succeed in achieving the desired object and public co-operation is necessary at every stage. It must therefore be admitted that in addition to the provisions of any law that has been or may have to be enacted, industry and trade as well as the consumer will also have to pay due consideration to their responsibility. Everybody will agree that the interests of manufacturers and traders will have to be safeguarded by any action to be taken to reach the desired goal but at the same time it must be our endeavour to ensure that there is not a large disparity between the cost of the article and the price at which it is sold to the public. The question should be one of "LIVE AND LET LIVE" I imagine, looking at the number of people engaged in the drug trade either as manufacturers, importers or dealers, that it is by no means unprofitable; indeed it holds our promise of good returns.

You are all doubtless aware of one of the very distressing features of the present day pharmaceutical trade. I refer to the adulteration resorted to by some unscrupulous people and the consequent unethical products which are sold and advertised to the public. I have

referred to these problems whenever I have had occasion to deal with the subject. In spite of the enforcement of the Drugs Act in most of the States, adulteration of some of the popular and costly medicines is still going on in many parts of the country. This is largely due to the activities of unsocial elements and partly to the non-enforcement of the Drugs Act in some of the States. I understand that steps are now being taken to implement the provisions of this Act in Part B and some Part C States. Apparently, this could not be achieved earlier owing to constitutional and other difficulties. But I am glad to say that there has been a general awareness in the minds of the authorities in the States that the sooner this legislation is effectively implemented in their regions the better it will be in the interests of the country as a whole. It has sometimes been said that the provisions of the law are not very rigorous. My Ministry is considering how to tighten the provisions of the legislation so as to make adulteration of drugs an unprofitable business and I hope that, in addition to the provisions of the law, we shall get the willing co-operation of both trade and the public in effectively putting down this evil.

I trust the Committee will go into the question as to what leads to the adulteration of drugs and suggest ways and means to eliminate the causes that lead to this evil and thus put a stop to such malpractices. You can imagine the feelings of a person who, having purchased a bottle of medicine, finds that it has had no effect on him. Apart from being cheated, a sense of distrust and discontent spreads in the public mind which is harmful to society. Not only on health grounds but even on social grounds the evil of adulteration must therefore be stopped. I may point out too that this evil strikes at the very root of scientific medical practice and thereby indirectly helps the development of quackery and charlatanism.

There must be a three-pronged attack on this evil—first as I said, by making the punishment under the Drugs Act deterrent, secondly by going into the causes that lead to adulteration as, for example, shortage of a particular brand of medicine and thirdly by prevailing on the medical profession to abstain from prescribing costly patent and proprietary medicines unless they are absolutely essential. There are a sufficient number of standard drugs included in the various Pharmacopoeias which should certainly satisfy the needs of the medical profession and the elimination of the patent and proprietary medicines will not in any way cause any hardship either to the doctor or to the consumer. I am sorry to have to say this but the medical profession are beginning to lose the art, as it were, of writing prescriptions and one wonders whether there may not often be even a link-up between them and the trade to enhance the sale of patent medicines. A great responsibility rests on doctors in this regard. The belief in patent medicines in the public mind has been caused by large amounts of money spent in advertisements whereby patients are led to believe that health can be purchased by procuring a bottle or a tin of patent medicine without even obtaining medical opinion. I do not wish to say that patent and proprietary medicines should be done away with altogether, particularly because, due to lack of medical personnel, such articles are sometimes useful in rural areas.

But what I would like to stress is the necessity of doing away with costly patent and proprietary medicines which are sold to the unwary public by the trade by spending huge amounts of money on advertisements as to their efficiency. Owing to the extensive attractive and often-times very misleading advertisements many people resort to self medication. There is more danger in this than people can believe. If a person resorts to self-medication merely on the claims made in the advertisement in regard to the efficacy of a particular remedy, it may at times even lead to disastrous consequences. If you open the pages of any newspaper or magazine or even read posters in the streets you will often find the most disguising type of advertisements. The unwary and the gullible both fall a prey to them and it is difficult to assess the damage thus caused. I have always felt that such advertisements are a real menace to society and I am glad to say that at long last I hope shortly to introduce legislation for regulating them. Apart from laws, however, manufacturers and other interested parties must also see to it that a healthy tone is maintained in public life and they co-operate with the Government in putting a stop to all unethical practices in the realm of medicines for the sick and ailing members of the public.

I am sure the Committee will go into the various aspects of the pharmaceutical trade, including the difficulties experienced by manufacturers and dealers, and suggest such ways and means as will enable Government to take action to meet the needs of the people in an atmosphere free from greed, graft or gain.

India has vast resources for development. In the pharmaceutical industry, in particular, it should be possible with concerted efforts to make India self-sufficient in drugs. In the matter of drugs of vegetable origin, there is no plant that cannot be grown in India and even in the present undeveloped stage, we have a store of most of the pharmaceutical drugs. To mention just a few, I would say that we are self-sufficient in the opium alkaloids, strychnine, caffeine, quinine etc. There is immense scope for developing others. In regard to products derived from animal origin, you are aware that our cattle wealth is the highest in the world. We have not, however, as yet made any concerted efforts to explore the possibility, with the exception of Liver Extract, of utilising our potential sources for making glandular products. In the field of chemotherapy, however, we are not as happily placed as I would like us to be. Modern therapy is helped greatly by chemotherapeutic and antibiotic drugs. Although the manufacture of penicillin under the auspices of the Government of India is in sight we have to go some way before we can to any extent claim self-sufficiency. The pharmaceutical industry in India must devote itself largely to research, develop new methods of production, synthesise newer and newer substances and try to keep abreast of the times. The present pharmaceutical industry consists mainly of bottling, ampouling or labelling of drugs made from imported raw materials. Although this by itself is no mean achievement and has greatly contributed to self-sufficiency in respect of finished goods, the efforts of our industrialists must be directed, as I have already said, more and more towards developing the pharmaceutical industry on sound lines and for that purpose we must find ways and means to have a stable basic chemical industry.

Raw materials will then *ipso facto* become available at competitive rates.

I wish the Committee success in the difficult task they have to tackle and I have every hope that through their deliberations India will soon be blessed with the basis of a strong and stable pharmaceutical industry.



सत्यमेव जयते

# APPENDIX No. 2-A

## THE DATES AND PLACES OF THE MEETINGS OF THE PHARMACEUTICAL ENQUIRY COMMITTEE

Meeting	Date	Place
First Meeting. . . . .	12-3-53	Delhi.
Second Meeting. . . . .	7-5-53	Bombay.
Third Meeting. . . . .	25-6-53	Bangalore.
Fourth Meeting. . . . .	10-8-53	Bombay.
Fifth Meeting. . . . .	14-9-53 & 17-9-53	Calcutta.
Sixth Meeting. . . . .	27-10-53	Hyderabad.
Seventh Meeting. . . . .	18-11-53 to 20-11-53	Delhi.
Eighth Meeting. . . . .	12-4-54 to 15-4-54	Delhi.
Ninth Meeting. . . . .	31-5-54 to 2-6-54	Bangalore.



सत्यमेव जयते



## APPENDIX No. 2-B

### THE NAMES OF THE MANUFACTURING CONCERNS, RESEARCH AND TESTING LABORATORIES AND OTHER INSTITUTIONS VISITED BY THE PHARMACEUTICAL ENQUIRY COMMITTEE

Date of visit	Place	Name of the Manufacturing concerns & other institutions visited	Name of the Research and Testing Laboratory visited
1	2	3	4
7-5-53	Bombay	Govt. Medical Stores	..
8-5-53	Do.	..	Haffkine Institute.
8-5-53	Do.	Indian Penicillin Committee (Bottling Plant)	..
8-5-53	Do.	Bombay Govt. Shark Liver Oil Factory.	..
"	Do.	Office of the Drugs Controller, Bombay State.	..
9-5-53	Do.	Manufacturing Analytical and Research Chemists Ltd., (MARC) (Owned & managed by Giba Pharma Ltd.)	..
"	Do.	..	Italab Ltd.
"	Do.	Teddington Chemical Factory	..
10-5-53	Do.	Dumex Limited	..
11-5-53	Do.	Glaxo Laboratories	..
12-5-53	Do.	Kemp & Co., Ltd.	..
"	Do.	Burroughs Wellcome & Co.	..
"	Do.	British Drug Houses	..
13-5-53	Do.	Chemical, Industrial, & Pharmaceutical Laboratories Limited. (CIPLA).	..
14-5-53	Do.	May and Baker (India) Ltd.	..
15-5-53	Do.	Raptakos, Brett Co., Ltd.	..
"	Do.	Unichem Laboratories	..
"	Do.	Boots Pure Drugs India Ltd.	..
16-5-53	Do.	Geigy Insecticides Ltd.	..
"	Do.	Amalgamated Chemicals & Dyestuffs Co. Ltd.	..
25-6-53	Bangalore	..	Indian Institute of Science
26-6-53	Do.	Industrial & Testing Laboratory Ltd.	..
"	Do.	..	Public Health Laboratory
27-6-53	Do.	Indian Process Chemical Laboratory.	..
"	Do.	Govt. Medical Stores	..

1	2	3	4
29-6-53	Mysore	Govt. Sandalwood Oil Factory	
29-6-53	Do.	.. . . .	Central Food Techno- logical Research Insti- tute.
30-6-53	Nilgiri Hills Naduvattam.	Govt. Quinine Factory . . .	
1-7-53	Coonoor	.. . . .	Pasteur Institute.
"	Do.	.. . . .	Nutrition Research La- boratories.
"	Do.	Royal Eucalyptus Oil Distillery	..
2-7-53	Kozhikode	Government Shark Liver Oil Factory.	
4-7-53	Madras	.. . . .	King Institute, Guindy.
6-7-53	Do.	Government Medical Stores	
20-7-53	Lucknow	.. . . .	Provincial Hygiene Insti- tute.
"	Do.	.. . . .	U. P. Govt. Public Analyti- cal Laboratory.
21-7-53	Do.	.. . . .	Central Drug Research Institute.
"	Do.	Aurora Laboratories	..
"	Do.	Imperial Surgical Co.	..
"	Do.	Rup Chemicals Ltd.	..
"	Do.	Vitamin Laboratories of India Ltd.	..
22-7-53	Kanpur	.. . . .	Ordnance Laboratories (Technical Development Establishment Labora- tories).
"	Do.	Hind Chemicals Ltd.	..
"	Do.	Bengal Chemicals and Pharmace- utical Works Ltd.	..
"	Do.	Ideal Chemical Works Ltd.	..
23-7-53	Amausi	Indian Medical Supply Labora- tories.	..
24-7-53	Bareilly	Rosin & Turpentine Factory	..
25-7-53	Izzetnagar (Bareilly)	.. . . .	Indian Veterinary Research Institute.
5-8-53	Madras	.. . . .	Madras Medical College.
5-8-53	Do.	Sandoz Products Ltd.	..
"	Do.	.. . . .	Stanley Medical College.
6-8-53	Bangalore	Ogale Glass Factory	..
7-8-53	Mandya (Mysore State)	Mandaya Sugar Factory . . .	..
7-8-53	Mysore	.. . . .	Medical College
8-8-53	Hyderabad	Taj Glass Works . . . . .	..
"	Do.	Biochemical & Synthetic Products Ltd.	..
"	Do.	Nath Laboratories	..
"	Do.	Pearl Surgical Co., Azamabad	..
"	Do.	Alcohol Laboratories, Narayan- guda.	..

1	2	3	4
12-8-53	Bulsar (Bombay State)	M/s. Atul Products.	..
"	Do.	Lederle (India) Laboratories Ltd.	..
14-8-53	Baroda	Alembic Glass Factory	..
"	Do.	Sarabhai Chemicals	..
"	Do.	Alembic Chemicals	..
15-8-53	Ahmedabad	..	Civil Hospital.
"	Do.	..	Medical College.
"	Do.	..	L. M. College of Pharmac
16-8-53	Baroda	Sanitex Chemical Industries Ltd.	
17-8-53	Do.	..	Medical College, & Sayaji General Hospital
18-8-53	Bombay	..	J. J. Hospital & Grant Medical College.
2-9-53	Amritsar	M/s. Surgical Dressings Manufacturing Co., Ltd.	Amritsar Medical College
"	Do.	Mehta Bros. Ltd.	
"	Do.	M/s. Shambu Nath & Sons	
3-9-53	Kasauli	..	Central Research Institute
11-9-53	Benaras	Vibhuti Glass Works	
12-9-53	Do.	..	Benaras Hindu University (Dept. of Pharmaceutics)
12-9-53	Ghazipur	Government of India Opium Factory & Alkaloid Works.	
14-9-53	Calcutta	Lister Antiseptics & Dressing Co. (India) Ltd.	
"	Do.	Indian Chemical & Therapeutic Works.	
15-9-53	Do.	Bengal Immunity Co., Ltd.	
16-9-53	Do.	Bengal Chemical & Pharmaceutical Works, Ltd.	
17-9-53	"	..	West Bengal Vaccine Institute.
"	Do.	..	Central Drug Laboratory.
"	Do.	..	All India Institute of Hygiene & Public Health.
18-9-53	Do.	Union Drug Co.	
"	Do.	East Indian Pharmaceutical Works.	
"	Do.	Smith Stanistreet & Co.	
"	Do.	Indian Health Institute	
19-9-53	Calcutta	Standard Pharmaceutical Works	
"	Do.	Brahmchari Research Institute	
"	Rishra (Calcutta)	Alkali and Chemical Corporation of India.	

1	2	3	4
21-9-53	Calcutta	Govt. Medical Stores	
"	Do.	Calcutta Chemical Co.	
"	Do.	Albert David	
"	Do.	Bathgate & Co.	
22-9-53	Calcutta		R. G. Kar Medical College (Pharmacology Department).
"	Do.		School of Tropical Medicine.
"	Do.	Tappassier Glass Works	
"	Do.	Gluconate Ltd.	
"	Do.	Sigcol Glass Works	
19-10-53	Trivandrum	Pharmaceutical & Chemicals (Trivandrum) Ltd.	
20-10-53	Trivella. (Travn-Cochin)	Travancore Sugar & Chemicals Ltd.	
21-10-53	Trivandrum		Medical College.
"	Do.		Public Health Laboratory.
"	Do.		University Chemical Research Laboratories.
"	Alwaye (Travn-Cochin State.)	Indian Rare Earths Ltd.	
"	Do.	Fertilizer & Chemical (Travancore) Ltd.	
"	Do.	Travancore-Cochin Chemicals Ltd.	
22-10-53	Perambavur (T. & C. State)	Travancore Rayons Ltd.	
23-10-53	Anamalai Hills	Quinine Factory and Cinchona Plantations.	
24-10-53	Coimbatore.		G. K. N. Memorial Hospital.
26-10-53	Hyderabad	Hyderabad Chemicals & Pharmaceuticals.	
"	Do.	Praga Tools, Hyderabad	
"	"	Hyderabad Laminated Products Ltd.	
27-10-53	"	Deccan Chemical Works	
"	Do.	Indian Chemicals & Pharmaceutical Works.	
"	Do.	Biochemical & Synthetic Products Ltd.	
27-10-53	Hyderabad		Laboratories for Scientific & Industrial Research

1	2	3	4
5-1-54	Bombay	. M/S. Geigy Insecticides Ltd., Bombay.	
6-1-54	Bombay	. Amrit Lal & Co.	
	Do.	. Bharat Pulverising Mills.	
	Do.	. Orient Industries.	
1-3-54	Calcutta	. A. P. V. Engineering Co. Ltd., Dum Dum.	
3-3-54	Dibrugarh	. James Warner & Co. Ltd.	
4-3-54	Shillong	.	Pasteur & Medical Research Institute,
5-3-54	Khasi Hills	Drug Plantations.	
6-3-54	Gauhati	. Assam Chemicals & Pharmaceuticals, Shantipur.	
	Gauhati	. Assam Research Chemicals, Chatribari.	
8-3-54	Mungpoo Latpanchar.	} Quinine & Ipecac Plantations.	
9-3-54	Rongo	. Drug Plantations.	



सत्यमेव जयते

### APPENDIX No. 3

#### *THE NAMES OF THE ASSOCIATIONS AND OTHER BODIES INTERVIEWED BY THE PHARMACEUTICAL ENQUIRY COMMITTEE*

Date of Meeting 1	Place 2	Name of the Association etc. interviewed. 3
9-5-53	Bombay	{ Minister for Industries & Health, Government of Bombay, Shri B. V. Patel Drugs Controller, Bombay State.
11-5-53	Do.	. Representatives of Customs Department, Bombay.
"	Do.	. Indian Chemical Manufacturers' Association (Bombay Branch).
"	Do.	. All India Manufacturers' Association, Bombay.
12-5-53	Do.	. Pharmaceutical & Allied Manufacturers' & Distributors Association, Bombay.
"	Do.	. Indian Pharmaceutical Association.
13-5-53	Do.	. Bombay Chemists & Druggists Association.
14-5-53	Do.	. Retail Chemists & Druggists Association, Bombay.
"	Do.	. Bombay Pharmaceutical Works Ltd, Bombay.
25-6-53	Bangalore	. Leading Medical Practitioners namely, Dr. B. K. Narayan Rao, Dr. D Siva Rao, Dr. Miss Albuquerque, and Dr. M. M. Mahadevan.
"	Do.	. Chemists & Druggists Association, Bangalore.
27-6-53	Do.	. Chief Minister and Minister for Health, Local Self Govt. and the Ministers for Home and Industry & Commerce, Shri B. R. Ramalinga Reddy, Director of Medical Services, Mysore Government.
4-7-53	Madras	. Chemists & Druggists Association, Madras.
"	Do.	. Indian Pharmaceutical Association, Madras.
6-7-53	Do.	. Ministers for Health, Finance, Commerce and Industry, Dr. M. V. Ramana murthi, Director of Medical Services Madras Government.
"	Do.	. Indian Medical Association, (Madras Branch).
20-7-53	Lucknow	. Minister for Industry, Health and Finance. U. P. Government.
"	Do.	. Indian Medical Association (Lucknow Branch).
"	Do.	. All India Chemists & Druggists Federation & Indian Pharmaceutical Association (U. P. Branch.)
21-7-53	Lucknow	{ Chief Minister, U P. Government, Col. A. N. Chopra, Director of Medical & Health Services and Dr. B. D. Wadhawa, Assistant Drugs Controller Uttar Pradesh.
"	Do.	. U. P. Pharmaceutical Manufacturers' Association.
22-7-53	Kanpur	. Indian Medical Association (Kanpur Branch).
"	Do.	. Chemists & Druggists Association (Kanpur).
8-8-53	Hyderabad	. Indian Medical Association (Hyderabad).
10-8-53	Bombay	. All-India Medical Licentiates' Association, Poona.
15-8-53	Ahmedabad	. Gujrat Chemists Mahamandal, Ahmedabad.
16-8-53	Baroda	. Chemists & Druggists Association, (Baroda Branch).
"	Do.	. Indian Pharmaceutical Association, (Baroda Branch).
"	Do.	. Indian Medical Association, (Baroda Branch).
2-9-53	Amritsar	. Chemists & Druggists Association, (Amritsar Branch.)
"	Do.	. Indian Medical Association, (Amritsar Branch.)

Date of Meeting. 1	Place 2	Name of the Association etc. interviewed. 3
4-9-53	Simla	Minister for Finance, and Secretary, Health Department, Punjab Government.
11-9-53	Benaras	Indian Medical Association (Benaras).
14-9-53	Calcutta	Indian Pharmaceutical Congress Association, Calcutta.
15-9-53	Do.	Chief Minister, Health Minister and Director of Industries, Dr. B. C. Das Gupta, Director of Health Services and Dr. Set, Drug licensing Authority Bengal Government.
"	Do.	Indian Medical Association, Calcutta.
16-9-53	Do.	Indian Chemical Manufacturers' Association, Calcutta.
17-9-53	Do.	Indian Chamber of Commerce, Calcutta.
"	Do.	Indian Pharmaceutical Association, (Calcutta Branch).
"	Do.	Chemists & Druggists Association, (Calcutta Branch).
19-9-53	Do.	Indian Pharmaceutical Manufacturers' Association, (Bengal Branch).
10-10-53	Delhi	Central Board of Revenue, Ministry of Finance. Government of India.
14-10-53	Delhi.	Chief Minister, Health Minister, Secretary, Industries & Local Self Government Departments of Delhi State.
19-10-53	Trivandrum	Secretary, Health Department and Surgeon-General Travancore-Cochin Government.
21-10-53	Alwaye (Travancore-Cochin).	Technical Association of Fertilizer Chemicals (Travancore-Ltd.)
27-10-53	Hyderabad	Minister for Health, Finance and Commerce, Dr. L. D. Khatri, Director of Health Services, Hyderabad Government.
28-10-53	Hyderabad	Chemists & Druggists Association, (Hyderabad Branch).
10-11-53	Delhi	Delhi Chemists & Druggists Association, Delhi.
17-11-53	Delhi	Joint meeting with Pharmaceutical and Allied Manufacturers, Distributors' Association and Indian Pharmaceutical Association.
	Bombay	Surgeon General (Dr. B. B. Dikshit) Government of Bombay.
5-1-54	Bombay	Dr. K. A. Hamied, of CIPLA Ltd., Bombay.
7-1-54	Bombay.	Dr. Venkataraman, Director of the Institute of Chemical Technology, Matunga.
"	Bombay	Discussion with nager, Government Shark Liver Oil Factory.
22-1-54	Delhi	Prof. Wayne of U. K.
3-2-54	Delhi	Prof. Schlittler and other representatives of M/s. Ciba Pharmaceutical Ltd., Bombay.
6-2-54	Delhi	Col. R. N. Chopra, Director, Drug Research Laboratory, Jammu.
26-2-54	Delhi	Dr. P. Das, Manager, Stadco Stores, Shillong.
4-3-54	Shillong	Chief Minister and Ministers for Health, Commerce and Industry and Finance, Dr. J. K. Saikia, Inspector-General of Civil Hospitals and Prisons Assam Government.
29-3-54	Delhi	Pharmaceutical and Drug Research Committee of the Council of Scientific and Industrial Research.
24-4-54	Chandigarh	Chief Minister and other officials of the Punjab Government.
5-5-54	Delhi	Lt.-General D. R. Thapar, Director General of Armed Forces.

## APPENDIX No. 4A

### QUESTIONNAIRE FOR INDUSTRY & TRADE

#### I. Classification of Manufacturers

(a) *Manufacturer*.—Do you manufacture any of the Pharmaceuticals in bulk out of those listed in Annexure (i) from primary indigenous raw materials, or (ii) from primary raw materials imported, or (iii) from intermediates imported or indigenous? A process is to be considered to be a manufacturing operation when one or more chemical operations are involved or products are manufactured from natural raw materials using extraction processes.

(b) *Manufacturer-cum-processor of finished drugs*.—Do you in addition to (a) process the pharmaceuticals in bulk produced by you further into finished packings like bottled drugs, single and compounded, injectibles, single and compounded, tablets or capsules, etc.?

(c) *Processing of finished drugs*.—Are you engaged only in preparation of drugs, single and compounded from basic pharmaceuticals imported or purchased locally from indigenous manufacturers falling under (a) above? No chemical operations are involved in the processing of drugs.

(d) *Processing of patented drugs*.—Are you a producer of (a) foreign, and (b) Indian patented drugs?

(e) *Importer-cum-manufacturer or packer*.—Are you an importer of finished drugs also apart from falling under (a), (b) or (c)?

*In each case give your answers with special reference to the annexure.*

#### II. Survey of the Industry

Give a short outline of the history of your establishment. The résumé may also refer to the following:—

(a) Year of establishment, present position in respect of capital invested, labour, technical personnel employed, power and fuel consumption, total value of raw materials consumed (indigenous and imported shown separately), annual sales, and profits or losses during the last five years, capital investment made in the last five years.

(b) Whether the establishment is now registered under the Industries (Development and Regulation) Act, 1951.

(c) Whether the establishment is also engaged in the manufacture of heavy chemicals, cosmetics, toothpastes and powders, etc., and if so, what is the proportion of sales of these products *vis-a-vis*

(d) Whether the establishment has any programme under implementation for the manufacture of (i) pharmaceuticals in bulk, (ii)



packing of pharmaceuticals indigenous and/or imported. When is the programme expected to be completed and production taken up? What is the capital investment involved?

(e) Whether the manufacturing programme under (d) is a phased programme and details relating thereto like processes proposed to be adopted, the specific products and quantities of each proposed to be manufactured.

(f) Whether the programme has been approved in entirety or in parts by the Government.

(g) Whether and what investment has been made by your firm so far in testing and research activities? What percentage does this investment bear to the annual turnover in the last ten years? As a result of the research work carried out by your firm, have you discovered any new drug which is either at par or higher in therapeutic efficiency than of the well recognised drugs already in use for the treatment of specific ailments? If so, give the details of such drugs. Compounded mixtures of existing drugs claiming improved therapeutic efficacy do not come under this category.

### III. Manufacture of non-Allopathic preparations

Is your establishment manufacturing or proposing to manufacture non-allopathic preparations? What is the total value of their output in relation to allopathic drugs manufactured?

### IV. Demand

What is your estimate of the present demand for the following drugs:—

(a) Anti-malarials as a whole as well as items like quinine, paludrine, etc.

(b) Anti-tubercular drugs as a whole as well as items like PAS, insonicotinyl hydrazide, etc.

(c) Antibiotics—Penicillin, Stereptomycin, Aureomycin, Chloromycetin, Terramycin.

(d) Shark liver oil and cod liver oil, vitamins in bulk.

(e) Sulpha drugs, break-up of demand *inter se* among the different sulpha drugs may be indicated.

(f) Anti-dysentric drugs—emetine hydrochloride, iodochloroxy quinoline.

(g) Analgesics—acetyl salicylic acid, phenacetin, etc.

(h) Insulin and anti-diabetic preparations.

(i) Anti-leprosy drugs.

(j) Liver Extract, oral and parenteral.

(k) Insecticides—break-up of demand in regard to D.D.T., B.H.C., etc., may also be indicated in addition to total demand.

(l) Disinfectants, break-up of demand in regard to phenyle, etc., may be indicated in addition to total demand.

### V. Single drugs, synthetic

(a) What is the annual production capacity in the case of the single drugs manufactured by your establishment from among those mentioned in the annexure? Indicate the basis of assessment of capacity specifying the number of shifts per day and the number of working days per annum assumed.

(b) Give a short description of the process adopted in their manufacture.

(c) What is the quantity of drugs produced in each of the last three years?

(d) Indicate the rate of consumption of major raw materials and the conversion efficiency of the process in every case. Among the raw materials, which are the ones that are imported? What is the customs duty on these and on the imports of the particular drug produced?

(e) What is the cost of production of each of the products manufactured by you mentioned above? Cost of production should be worked so as to provide for the expenditure on raw materials, labour and technical personnel employed on the process, fuel including steam and electricity, containers and packing materials, depreciation on plant, interest on working capital. What is the price at which the drug is sold in bulk for further processing and manufacture of finished drugs?

(f) If the drug is further processed in the same establishment and sold in the form of finished drug, what is the additional cost involved? The second-half of 1952 may be taken as the period for assessment of cost of production.

(g) In case of drugs whose production is under development, replies to the above may be given on the basis of plans formulated and estimates of cost.

### V. Single drugs of vegetable origin and animal origin derived from primary raw materials

(a) What is the annual production capacity of the drugs manufactured by your firm with special reference to the items mentioned in annexure? Indicate the basis of assessment of capacity specifying the number of shifts per day and the number of working days per annum assumed.

(b) Indicate separately in terms of quantities and sale value, a drug of vegetable and animal origin produced by your firm during each of the last three years whose value of output exceeds Rs. 25,000 per annum.

(c) Give the quantities of different raw materials consumed in respect of each drug under (b), and the duty on imported raw materials consumed.

(d) What is the cost of production of each product mentioned under (b)? Calculate the cost as suggested in V (e), (f) and (g).

### **VII. Compounded Drugs with Disclosed Formulæ**

(a) What is the total value of compounded drugs with disclosed formulæ produced by your firm during the last three years?

(b) Mention the compounded drugs manufactured by your firm in accordance with specifications in force and the production capacity in each case.

(c) Indicate separately in terms of quantities and sale value, compounded drugs produced by your firm during each of the last 3 years whose value of output exceeds Rs. 25,000 per annum.

(d) What is the cost of production of each product under (c)? Calculate the cost as suggested in V (f) and (g).

### **VIII. Patent Medicines with undisclosed formulæ**

(a) Mention the important medicines with undisclosed formulæ being produced by you.

(b) In case of preparations whose annual sale exceeds Rs. 25,000, indicate the products with the quantities of each produced during each of the last three years and the corresponding sale value.

(c) What is the cost of production of each product mentioned under (b)? Calculate the cost as suggested in V(e), (f) and (g).

### **IX. Capacity in existence for processing of drugs**

(a) What is the installed capacity of your establishment for the following processing operations:—

(i) Tableting of drugs

(ii) Ampouling

Indicate the basis on which the capacity has been assessed—number of shifts per day and number of working days per annum.

### **X. Disinfectants, insecticidal preparations and anti-malarials**

(a) What are the disinfectants, insecticidal preparations and anti-malarials which you manufacture and their annual sale value?

(b) Indicate separately in terms of quantities and sale value, the various products produced by you during each of the last 3 years whose value of output exceeds Rs. 25,000 per annum.

(c) What is the cost of production of each of the products mentioned under (b)? Calculate the cost suggested under V (f) and (g).

### **XI. Advertisement of drugs**

(a) What is the amount spent by the establishment on advertisement of drugs during the last five years? What is its proportion to total sales? Out of the total advertisement expenditure, what is the proportion spent on newspaper advertisements?

(b) Take a few preparations whose sale value exceeds Rs. 25,000 and indicate the relationship between advertisements and sales development over a period.

**XII. What are your views on the Development of the repacking industry, particularly in regard to dated products?**

**XIII. Imports of drugs and pharmaceutical in bulk and intermediates**

(a) What are your views on the essentiality of imported patent drugs?

(b) What should be the import policy in regard to (a) above?

(c) What changes in import policy and tariffs in the field of pharmaceuticals do you consider necessary for development of the pharmaceutical industry?

**XIV. What in your opinion are steps that should be taken for the following:—**

(a) Manufacture of important drugs in the country.

(b) Regulating the development of the drug industry along healthy lines.

(c) Ensuring the availability to the consumer of drugs of proper quality at reasonable prices.

(d) Combating the evils of spurious drugs and adulteration of drugs.

**XV. Tie-up between Indian and foreign concerns or their subsidiaries in the manufacture of drugs.**

(a) Has your firm entered into any agreement with a foreign company or its subsidiary operating in India for the purpose of manufacturing drugs? If so, send a copy of the agreement as agreed to by the Government.

(b) What is the amount of royalty paid annually in the past to the foreign collaborators as per terms of the agreement? Based on the manufacturing programme, what will be the amount of royalty to be paid annually during the next five years?

**XVI. Scheme of Distribution**

(a) Apart from being a manufacturer, are you engaged in the distribution of your products also? If so, please give a short outline of your organisation indicating briefly the margin between the cost of production and the price for the consumer

(b) Do you distribute your products through:—

(i) Subsidiary companies of your own or other firms

(ii) Distributing agents

(iii) Direct to trade


What are the terms of agreement between you and the distributing parties?

(c) (i) Do you publish a price list? If so, does it give: (i) the price to the consumer, or (ii) the price to the trade? Please send two copies of the latest price list.

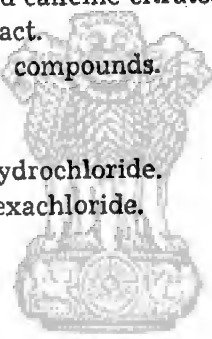
(ii) Do you have a fixed mark up to arrive at this price based on landed cost of the imported finished product or the cost of production of the finished product ex your warehouse?

- (iii) What are the scale of trade discounts, if any, on (i) retail price of the consumer to the trade, (ii) the discount to your distributor, if any, on the price at which the trade is supplied?
- (iv) What is your mark up on landed cost or warehouse to arrive at the consumer's price in the following categories of drugs:—
- (1) Antibiotics; Penicillin and preparations thereof; Streptomycin and preparations thereof; Aureomycin and preparations thereof; Terramycin and preparations thereof; Chloramphenicol; other antibiotics.
  - (2) Sulpha drugs and their preparations
  - (3) Vitamins and their preparations
  - (4) Synthetic anti-malarial drugs like paludrine
  - (5) Insecticidal preparations
  - (6) Para-aminosalicylic acid and salts.
  - (7) Isonicotinyl hydrazide

#### ANNEXURE

- 
1. Iodochlor-oxyquinoline.
  2. Di-iodo-oxyquinoline.
  3. Carbarsone.
  4. Neoarsphenamine.
  5. Sulpharsphenamine.
  6. Chlorobutanol.
  7. Cinchophen.
  8. Nicotinic acid.
  9. Nikethamide.
  10. Para-aminosalicylic acid.
  11. P-acetyl amino benzaldehyde thiosemicarbazone.
  12. Novophone (Diaminodiphenyl Sulphone).
  13. Luminal—Barbiturates.
  14. Argenti Proteinus.
  15. Potassium citrate.
  16. Sodium salicylate.
  17. Epsom salt.
  18. Silver Nitrate.
  19. Potassium Bromide.
  20. Ammonium Bromide.
  21. Sodium Bromide.
  22. Chloral hydrate.
  23. Ether.
  24. Ethyl Chloride.
  25. Chloroform.

26. Calcium lactate.
27. Sulpha pyridine.
28. Sulphadiazine.
29. Sulphathiazole.
30. Iron ammonium citrate.
31. Penicillin.
32. Aureomycin.
33. Streptomycin.
34. Chloromycetin (Chloramphenicol).
35. Folic acid.
36. Isonicotinyl hydrazide.
37. Saccharine.
38. Acetyl salicylic acid.
39. Shark liver oil.
40. Quinine and its salts.
41. Caffeine and caffeine citrate.
42. Liver' Extract.
43. Adrenaline compounds.
44. Ephedrine.
45. Codeine.
46. Emetine hydrochloride.
47. Benzene hexachloride.
48. D.D.T.
49. Phenyle.
50. Paludrine.



सत्यमेव जयते

## APPENDIX No. 4B

### QUESTIONNAIRE FOR MEMBERS OF THE MEDICAL PROFESSION, PUBLIC HEALTH AUTHORITIES, ETC.

Note:—Detailed answers are requested with particular reference to the List of drugs appended.

#### 1. Availability and Use of Drugs

(a) Give your views on the present position of availability of drugs required by you in your professional work. If you are not satisfied with their availability, please indicate the groups of drugs as well as any particular drugs whose supply is not satisfactory and the reasons therefor.

(b) Broadly state the proportion of drugs of indigenous manufacture and of imported origin that are used by you.

#### 2. Quality and Testing of Drugs

(a) Are you satisfied with the quality of drugs used by you?

(b) How do you control the therapeutic results:

(i) Clinically or (ii) by special tests or by both (i) and (ii)?

(c) Can you suggest improvements in regard to the methods of controlling the efficacy of drugs?

#### 3. Essentiality and Import of Drugs

(a) Do you think that the drug market is full of a large number of foreign drugs that the country can do without? If so, what steps would you advise to determine which are essential?

(b) Covering the groups mentioned in Appendix, give a short list of drugs which must be imported. In suggesting the list you may bear in mind the finished drugs of an equivalent nature and comparable quality being produced in the country.

4. Do you use drugs manufactured in India? If so, give a list of the main drugs.

5. Give detailed information regarding specific drugs falling under the following categories which you use from the point of view of their absolute necessity for the country. Even among essential drugs, give your order of preference:—

(a) Antibiotics

(b) Other antibacterial chemical drugs

(c) Combinations

(d) Other drugs

6. Have you in your professional capacity come across any misuse of drugs? If so, give details.

7. What are your views regarding vitamin combinations? Are all the combinations that are imported or indigenously produced necessary? Please give a list of the most important combinations that you would like to be made available for use.

8. What are your views regarding different 'patent' and proprietary names for the same drugs.

9. To what extent does it lead to wastage of drugs and hence of foreign currency?

10. Would you like the Pharmacopoeial name or suitable chemical name first wherever possible and the trade mark or patent name beneath it in smaller letters? Would this procedure save wastage?

### **11. Advertisement of Drugs**

(a) What are your views regarding present methods used in advertising drugs?

(b) Are you in favour of restriction or ban on advertisement of medicines in lay press?

(c) Do you consider it necessary that costly illustrated advertisements should be sent to you frequently?

(d) Will your efficiency as a medical practitioner suffer if you do not receive them as elaborately and frequently as at present?

(e) Do you think that claims made for some of the drugs are exaggerated? If so, give an illustrative list.

### **12. Machinery for Selection of Drugs for Import**

(a) Can you suggest a machinery by which selection of drugs for absolutely necessary imports could be made without much delay?

(b) Should such a machinery be 'official' or 'non-official'?

(c) Do you think that the medical associations in the country can undertake this work?

### **13. Restriction of Range of Production of Household Remedies**

(a) You are aware that a large number of prescriptions such as cough mixtures, diarrhoea mixtures, etc., are imported and/or compounded in the country. Do you think that it would be in the interest of better medical practice to restrict these?

(b) Please give a short list of these household remedies which you think are essential for use.

14. Is it desirable that a National Formulary be prepared in India? What should be its scope with reference to 13(a) and (b)?

### *Representative List of Drugs*

#### **1. Antibiotics**

(a) Penicillin and preparations thereof

(b) Streptomycin and preparations thereof

(c) Aureomycin and preparations thereof

(d) Chloramphenicol



- (e) Terramycin and preparations thereof
- (f) Other antibiotics and preparations thereof
- 2. Sulpha Compounds**
  - (a) Sulphathiazole
  - (b) Sulphadiazine
  - (c) Sulphaguanidine
  - (d) Sulphapyridine
  - (e) Other sulpha compounds
- 3. Vitamins and Preparations thereof**
  - (a) Shark Liver Oil, Cod Liver Oil
  - (b) Formulations of vitamins or single vitamins
- 4. Anti-Malarials**
  - (a) Quinine and its salts.
  - (b) Paludrine
  - (c) Other anti-malarials
- 5. Glandular Products and Biologicals**
  - (a) Liver Extract and its preparations
  - (b) Adrenaline compounds
  - (c) Hormone preparations
  - (d) Insulin
- 6. Anti-Tubercular Drugs**
  - (a) Para-amino salicylic acid and its salts
  - (b) Isonicotinyl hydrazide
  - (c) Other anti-tubercular compounds
- 7. Anti-Dysentric Preparations**
  - (a) Emetine compounds.
  - (b) Isonicotinyl hydrazide
  - (c) Other preparations
- 8. Colloidal Preparations**
- 9. Analgesics, Soporotics and Anæsthetics**
  - (a) Analgesics—Aspirin and preparations thereof
  - (b) Soporotics—Luminal, barbiturates, etc.
  - (c) Anæsthetics—(i) General:—Chloroform, ether, ethyl chlo  
ride, etc., (ii) Local:—Cocaine, novocaine, etc.
- 10. Cardiac Stimulants**
  - (a) Coramine
- 11. Anti-Leprotic Drugs**
  - (a) Sulphones
- 12. Disinfectants and Insecticidal Preparations**
  - (a) D.D.T. and B.H.C. formulations. simple and mixec

#### APPENDIX No. 4 C.

##### QUESTIONNAIRE FOR THE WHOLESALE & RETAIL TRADE.

1. Please state whether you are a wholesale or retail distributor of drugs and since when you have been in this line.

2. If you are both a wholesaler and retailer, give separately the volume of wholesale transactions and retail transactions during the last three years.

3. Do you hold the view that it is not desirable or practicable to restrict distributors exclusively to be wholesalers or retailers? If so, please state the reasons therefor. Is it desirable to apply this principle on a qualified basis, for example, in large cities?

4. Give short description of the organisation of your system of distribution dealing *inter alia* with the following:—

(a) The number of depots and branch depots in case of wholesalers and number of chemists shops in case of retailers.

(b) Personnel employed and wages and salaries.

(c) Whether you maintain pharmacists and their salaries.

(d) Working capital invested in the business by you and the gross and net profit.

(e) Margin allowed (i) by importers if you are a wholesaler and (ii) by wholesalers if you are a retail chemist.

(f) Volume of trade in Indian allopathic drugs and imported drugs handled by you.

5. Are you a member of a recognised association?

6. What in your view should be the optimum ratio between population and retail chemists shops?

7. What changes do you consider to be necessary in so far as licensing of wholesale and retail trade is concerned (a) to ensure fair margins of profit (b) to prevent the sale of spurious drugs.

## APPENDIX No. 5A.

LIST ILLUSTRATING THE NAMES OF ORGANIC AND INORGANIC CHEMICALS WHICH ARE REQUIRED BY THE PHARMACEUTICAL INDUSTRY BUT THE PRODUCTION OF WHICH THE INDUSTRY NEED NOT TAKE UP.

Ammonia.  
Acetone.  
Arsenious Oxide.  
Ammonium Nitrate.  
Ammonium Sulphate.  
Acetic Acid.  
Acetic Anhydride.  
Ethyl Alcohol.  
Methyl Alcohol.  
Bleaching Powder.  
Bromine.  
Benzene.  
Chlorine.  
Caustic Soda.  
Carbon-di-oxide.  
Chlorosulphonic Acid.  
Copper Sulphate.  
Calcium Cyanide.  
Caustic Potash.  
Chromic Acid.  
Carbon-di-Sulphide.  
Calcium Chloride.  
Common Salt.  
Ferric Chloride.  
Formaldehyde.  
Gelatine.  
Glycerine.  
Hydrochloric Acid.  
Hydrobromic Acid.  
Iodine.  
Potassium Iodide.  
Magnesium Chloride.  
Magnesium Sulphate.  
Nitric Acid.



सत्यमेव जयते

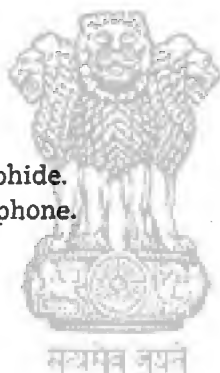
Pot. Di Chromate.  
Phosphorous Oxy Chloride.  
Phosphoric Acid.  
Pot. bi-Carbonate.  
Pot. Cyanide.  
Pot. permanganate.  
Pyridine.  
Pot. hydroxide.  
Sulphuric Acid.  
Soda Ash.  
Sodium Nitrate.  
Sodium Nitrite.  
Sodium bi-Sulphite.  
Toluene.  
Urea.  
Thiourea.  
etc.



## APPENDIX NO. 5B.

LIST ILLUSTRATING THE NAMES OF FINE CHEMICALS AND DRUGS WHICH THE PHARMACEUTICAL INDUSTRY SHOULD MAKE AN EFFORT TO MANUFACTURE.

Amino-5-ethyl amino pentone.  
Anilic Acid.  
Arsenalic Acid.  
Amyl Acetate.  
Aceto Phenone.  
Acetyl Sulphaguanidine.  
Acetyl Sulphathiazole.  
Acetyl Sulphadiazine.  
Benzyl Chloride.  
Benzyl Cyanide.  
5-Chloro-8-hydroxyquinoline.  
Chloroform.  
Chloral.  
Chloro Nitro-benzene.  
Chlorobenzene.  
Chloral hydrate.  
Di-Nitro-di-phenyl Sulphide.  
Di-Nitro-di-phenyl Sulphone.  
Diethylamine ethanol.  
Di-Chloro ethylamine.  
Diethyl Oxalate.  
Di-methyl aniline.  
Ethyl nicotinate.  
Ethyl Isonicotinate.  
Ether.  
Ethyl Iodide.  
Ethyl Phenyl Acetate.  
Ethyl Phenyl di-ethyl melonate.  
Ethyl Acetate.  
Ethyl formate.  
Ethyl Aceto Acetate.  
Ethoxy methylene.  
Gamma-picoline.  
4-hydroxy-7-Chloroquinoline.



8-Hydroxyquinoline.  
 Hydrazine Hydrate.  
 Hydroxylamine.  
 Isonicotinic Acid.  
 Isatin.  
 Isopropylamine.  
 m-Aminophenol.  
 Methyl benzene Sulphonate.  
 Morphine.  
 Nicotinic Acid.  
 Nitro benzene.  
 Nicotinic Acid Chloride.  
 O-toluene Sulphonamide.  
 O-toluene Sulphanyl Chloride.  
 Ortho Nitro Phenol.  
 Ortho Amino Phenol.  
 p-Chlorophenyl di-cyandiamide.  
 p-Chlorophenol.  
 p-Chloro-o-nitrophenol.  
 p-Chloro-o-Aminophenol.  
 p-toluene Sulphonyl Chloride.  
 Potassium Xanthate.  
 Phenyl diethyl Nitrate.  
 p-Anisidine.  
 p-Acetanilide Sulphonyl Chloride.  
 Salicylic Acid.  
 Sodium Aceto Acetic Ester.  
 Thionyl Chloride.  
 etc.

## APPENDIX No. 6.

### STATEMENT SHOWING THE BRITISH PHARMACOPOEIAL DRUG PLANTS AND THEIR SUBSTITUTES GROWING IN INDIA

Name of the State	Name of the Medicinal Plant	Place/District
1	2	3
ASSAM	1. <i>Anethum graveolens</i> Linn. (Umbelliferae) Vernacular names: Shulpa, Soya	Goalpara Dist., Lakhimpur Dist., Darrang Dist.
	2. <i>Camellia Sinensis</i> Linn. O. Kuntze (Theaceae). Vernacular name : Cha.	Abor Hills, Golaghat, Sibsagar Dist., Khasi and Jaintia Hills, Naga Hills, Lakhimpur Dist., Jarsain, Shillong.
	3. <i>Cassia Fistula</i> Linn. (Legu- minosae) (B.P. 1932). Vernacular names: Sonali, Amaltas, Aragoram.	Kamrup Dist., Lower Hills, Khasi & Jaintia Hills, Sibsagar, Sylhet.
	4. <i>Chenopodium album</i> Linn. (Chenopodiaceae). Vernacular names: Bathusag, Chakwit, Parupukkirai.	Dibrugarh, Dhubri, Goalpara Naga Hills, Kohima to, Nerhema Makum, Abor, Khasi Hills, Soo- bhan river on banks, Udal- guri
	5. <i>Cinnamomum Camphora</i> Nees and Eberm. (Lauraceae). Vernacular names: Karpur, Kapur, Karpuram.	Murkong Selek, Sadiya Fron- tier Tract, Myllem, Khasi & Jaintia Hills, Shillong.
	6. <i>Cinnamomum Zeylanic</i> Nees (Lauraceae). Vernacular names: Dalchini, Ilavangam.	Sibsagar, Khasi & Jaintia Hills.
	7. <i>Citrus aurantium</i> Linn. (Rutaceae). Vernacular names: Kamla nambu, Narangi, Sangtara, Narangam.	Assam State.
	8. (a) <i>Datura Stramonium</i> Linn. (Solanaceae). (b) <i>Datura tatula</i> Linn. (Solanac- eae). Vernacular names: Sada dhutura, Dhattura, Umattaka.	Khasi Hills, Nowgong, Shillong.
	9. <i>Erythroxylum Coca</i> Lam. (Erythroxylaceae). Vernacular name: Sivadari.	Nowgong District.
	10. <i>Eucalyptus globulus</i> Labill: (Myrtaceae). Vernacular name: Karupurama- ram.	Khasi & Jaintia Hills.

1	2	3
ASSAM— <i>contd.</i>	11. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae).	Nowgong District, Kamrup plains.
	Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.	
	12. <i>Linum usitatissimum</i> Linn. (Linaceae) (B.P. 1932).	Kamrup Dist., Sibsagar Dist., Luhit Valley, Darrang Dist.
	Vernacular names: Tisi, Alasi, Alsi, Alshi.	
	13. <i>Papaver Somniferum</i> Linn. (Papaveraceae).	Aka Hills.
	Vernacular names: Post, Afim, Postaka.	
	14. <i>Picraena quassioides</i> Benth. (Simarubaceae).	Khasi & Jaintia Hills, Naga Hills.
	Vernacular names: Bhurungi, Bharangi, Bering.	
	15. <i>Pinus Longifolia</i> Linn. (Coniferae).	Balipara Frontier Tract.
	Vernacular names: Saralagach, Chil, Simaidevadari.	
	16. <i>Polygala Chinensis</i> Linn. (Polygalaceae).	Khasi Hills, Mishmi Hills.
	Vernacular name: Meraqu.	
	17. <i>Punica granatum</i> Linn. (Lythraceae).	Shillong.
	Vernacular names: Dalingachh, Dalimba, Anar, Madulam.	
	18. <i>Ricinus Communis</i> Linn. (Euphorbiaceae).	Abor Hills, Khasi & Jaintia Hills.
	Vernacular names: Bherenda, Erendi, Arend, Attagam.	
	19. <i>Tamarindus Indica</i> Linn. (Leguminosae).	Kamrup Dist., Naga Hills, Sibsagar.
	Vernacular names: Tentul, Amli, Imli, Amilam.	
	20. <i>Acacia Catechu</i> Willd. (Leguminosae).	Darrang, Kamrup Dist., Khasi and Jaintia Hills, Goalpara Dist., Sadiya, Sibsagar.
	Vernacular names: Kuth, Khai- ra, Khair, Karungali.	
	21. <i>Valeriana Wallichii</i> DC. (Valerianaceae).	Khasi & Jaintia Hills, Naga Hills.
	Vernacular names: Mushkbura, Tagara.	
BIHAR	1. <i>Camellia Sinensis</i> Linn. O. Kuntze (Theaceae).	Parasnath Hills, Hazaribagh Dist.
	Vernacular name: Cha.	
	2. <i>Cassia fistula</i> Linn. (Legu- minosae) (B.P. 1932).	Manbhum Dist., Santal Par- ganasa.
	Vernacular names: Sonali, Amaltas, Aragoram.	
	3. <i>Chenopodium Album</i> Linn. (Chenopodiaceae).	Manbhum.
		Vernacular names: Bathusag, Chakwit, Parupukkirai.



1	2	3
BIHAR— <i>contd.</i>	<p>4. (a) <i>Datura Stramonium</i> Linn. (Solanaceae). (b) <i>Datura tatula</i> Linn. (Solanaceae). Vernacular names: Sada dhutura, Dhattura, Umattaka.</p> <p>5. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae). Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.</p> <p>6. <i>Linum usitatissimum</i> Linn. (Linaceae). (B. P. 1932). Vernacular names: Tisi, Alasi, Alsi, Alshi.</p> <p>7. <i>Papaver somniferum</i> Linn. (Papaveraceae). Vernacular names: Post, Afim, Postaka.</p> <p>8. <i>Pinus longifolia</i> Linn. (Coniferae). Vernacular names: Saralagach, Chil, Simaidevadari.</p> <p>9. <i>Polygala chinensis</i> Linn. (Polygalaceae). Vernacular name: Meradu.</p> <p>10. <i>Punica granatum</i> Linn. (Lythraceae). Vernacular names: Dalimgachh, Dalimba, Anar, Madulam.</p> <p>11. <i>Ricinus Communis</i> Linn. (Euporbiaceae). Vernacular names: Bhrenda, Erendi, Arend, Attagam.</p> <p>12. <i>Acacia catechu</i> Willd. (Leguminosae). Vernacular names: Kuth, 'Khaira, Khair, Karungali.</p> <p>13. <i>Urginea indica</i> Kunth (Liliaceae). Vernacular names: Ban piaz, Jangli piaz, Narivengayam.</p>	<p>Ranchi ghats.</p> <p>Chota Nagpur, Purnea Dist., Singhbhum Dist., Manbhum, Palamau.</p> <p>Champaran, Darbhanga, Gaya, Saran, Muzaffarpur.</p> <p>Chapra, Gaya, Monghyr, Motihari, Patna, Tirhut.</p> <p>Purneah (Cult.), Ranchi (Cult.), Sameshwar hills—Champaran.</p> <p>Chota Nagpur, Darbhanga, Manbhum Dist., Monghyr, Nathpur.</p> <p>Chota Nagpur, Hazaribagh, Ranchi.</p> <p>Bhagalpore, Hajipur, Muzaffarabad Dist., Monghyr, Patna, Purnea, Ranchi, Sitamarhi.</p> <p>Chota Nagpur, Gaya, Hazaribagh, Santal Parganas Dist., Monghyr, Palamau Dist.</p> <p>Mayurbhanj State, Palamau, Santal Parganas Dist., Ranchi, Singhbhum.</p> <p>Baroda, Ahmedabad Dist.</p> <p>Ahmedabad, Ahmadnagar, Gujarat, Dharwar, Khandesh, Poona, Sholapur, Surat.</p> <p>Ahmedabad, Gujarat College garden, Bombay Gardens.</p>
BOMBAY	<p>1. <i>Acacia Senegal</i> Willd. (Leguminosae). Vernacular names: Kumta, Sveta, Khadira Khor.</p> <p>2. <i>Acacia arabica</i> Willd. (Leguminosae). Vernacular names: Babul, Kikar, Karuvel.</p> <p>3. <i>Aloe barbadensis</i> Mill. (Liliaceae). Vernacular names: Ghirtakumari, Ghi-kavar, Kattalai.</p>	

1	2	3
BOMBAY— contd.	4. <i>Anethum Graveolens</i> Linn. (Umbelliferae). Vernacular names: Shulpha, Soya.	Baroda, Bombay, Matheran, Poona, Sholapur.
	5. <i>Arachis hypogaea</i> Linn. (Leguminosae). Vernacular names: Chiner badam, Bhui muga, Mungphali, Nilakkadalai.	West & East Khandesh, Satara, Sholapur, Bijapur, Belgaum.
	6. <i>Capsicum minimum</i> Roxb. (Solanaceae). Vernacular names: Lanka morich, Gach marich, peymilaga.	Borders of fields—Bombay.
	7. <i>Cassia angustifolia</i> vahl. (Leguminosae). Vernacular names: Sonpat, Hindi sana, Nila virai.	Poona Dist.
	8. <i>Cassia fistula</i> Linn. (Leguminosae). (B.P. 1932.) Vernacular names: Sonali, Amaltas, Aragoram.	Bijapur Dist., Poona Hills, Baroda.
	9. <i>Chenopodium album</i> Linn. (Chenopodiaceae). Vernacular names: Bathusag, Chakwit, Parupukkirai.	Kathiawar.
	10. <i>Cinnamomum Zeylanicum</i> Nees (Lauraceae). Vernacular names: Dalchini, Ilavangam.	North Kanara Dist.
	11. <i>Citrullus Colocynthis</i> Schrad (Cucurbitaceae). Vernacular names: Makhal, Indrayan, Peykumutti.	Ahmedabad.
	12. <i>Citrus aurantium</i> Linn. (Rutaceae). Vernacular names: Kamla nembu, Narangi, Sangtara, Naran- gam.	Bombay State.
	13. <i>Citrus medica</i> Linn Var. <i>Limonum</i> Linn. (Rutaceae). Vernacular names: Bara nebu, Gulgul, Madulam, Bara nimbu.	Bombay State.
	14. <i>Elettaria Cardamomum</i> Maton Var. <i>Minuscula</i> Brukill. (Zingiberaceae). Vernacular names: Elachi, Ila- chi, Chhoti elachi, Ilanji.	North Kanara Hilly Tracts.
	15. <i>Erythroxylum coca</i> Lam. (Erythroxylaceae).	Bombay Victoria gardens, Baroda College Botanical garden.

1	2	3
<b>BOMBAY—</b> <i>contd.</i>	Vernacular names: Sivadari. 16. <i>Hydnocarpus Wightiana</i> Blume (Bixaceae).	Bombay, North Kanara Dist.
	Vernacular names: Chaulmugra, Kauti, Garudaphala, Mara- vetti.	
	17. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae)	Konkan, North Kanara Dist., Thana Dist., Ahmedabad Dist.
	Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.	
	18. <i>Linum Usitatissimum</i> Linn. (Linaceae). (B. P. 1932).	Baroda, Ahmedabad, Bijapur, Dharwar, Khandesh, Nasik.
	Vernacular names: Tisi, Alasi, Alsi, Alshi.	
	19. <i>Lobelia nicotianifolia</i> Hey- ne. (Campanulaceae).	Poona Dist., North Kanara Dist., Launavada-Rewa Kantha
	Vernacular names: Nala, Dawal, Kuttuppugaiylai.	Agency, Sitara Dist.
	20. <i>Papaver Somniferum</i> Linn. (Papaveraceae).	Baroda College Nursery Baroda.
	Vernacular names: Post, Afim, Postaka.	
	21. <i>Polygala Chinensis</i> Linn. (Polygalaceae).	Belgaum, Panch Mahals, Guja- rat, Poona, Southern Marahatta
	Vernacular name: Meradu.	country, West Khandesh Dist.
	22. <i>Punica granatum</i> Linn. (Lythraceae).	Poona Dist., Sholapur.
	Vernacular names: Dalimgachh, Delimba, Anar, Madulam.	
	23. <i>Ricinus Communis</i> Linn. (Euphorbiaceae).	Baroda, Ahmedabad, Ahmad- nagar, Kanara, Khandesh, Kol- hapur, Kathiawar, Satara, Surat.
	Vernacular names : Bherenda, Brendi, Arend, Attagam.	
	24. <i>Santalum album</i> Linn. (San- talaceae).	Baroda College Botanical garden Baroda, Dharwar, Ahmedabad.
	Vernacular names: Chandan, Ingam.	
	25. <i>Strychnos nux—</i> Vomica Linn. (Loganiaceae).	Kanara Division.
	Vernacular names: Kuchila, Kara, kuchla, karalam.	
	26. <i>Tamarindus indica</i> Linn. (Leguminosae).	Ahmedabad, Bijapur, Dharwar, Poona.
	Vernacular names: Tentul, Amli, Imli, Amilam.	
	27. <i>Theobroma cacao</i> Linn. (Sterculiaceae).	Bombay Victoria Gardens.
	28. <i>Trachyspermum ammi</i> (Linn.) sprague (Umbelliferae).	Baroda, Sholapur.
	Vernacular names: Jowan, Aj- wan, Ajwain, Amam.	
	29. <i>Acacia catechu</i> Willd (Leguminosae).	Baroda, Ahmedabad, Broach forests, Thana Dist., Gujarat,

1	2	3
<b>BOMBAY—</b> <i>contd.</i>	Vernacular names: Kuth, Khaira, Kair, Karungali.	Kanara North, Khandesh, Kon- kan, Surat, Panchmahal forests, Poona, South Marhatta country.
	30. <i>Urginea Indica</i> Kunth (Liliaceae).	Harni on the coast below Bombay.
	Vernacular names: Ban piaz, Jangli piaz, Narivengayam.	
<b>MADHYA PRADESH.</b>	1. <i>Acacia arabica</i> Willd. (Leguminosae).	Akola, Yeotmal Dist.
	Vernacular names: Babul, Ki- kar, Karuvel.	
	2. <i>Arachis hypogaea</i> Linn. (Leguminosae).	Buldana, Akola, Amraoti, Nimar.
	Vernacular names: Chiner badam, Bhui muga, Mungphali, Nilakkadalai.	
	3. <i>Cassia fistula</i> Linn. (Le- guminosae).	Jubbulpore.
	Vernacular names: Sonali, Amaltas, Aragoram.	
	4. <i>Citrullus colocynthis</i> Sch- rad (Cucurbitaceae).	Chanda.
	Vernacular names: Makhal, Ind- rayan, Peykumutti.	
	5. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae).	Saugor, Jubbulpore, Narsingh- pur forest division, Yeotmal.
	Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.	
	6. <i>Linum usitatissimum</i> Linn. (Linaceae). (B.P. 1932).	Akola, Amraoti, Balaghat, Bhan- dara, Bilaspur, Buldana, Chanda, Damoh, Jubbulpore, Nagpur, Raipur, Saugor, Wun.
	Vernacular names: Tisi, Alasi, Alsi, Alshi.	Hoshangabad Dist.
	7. <i>Lobelia nicotianifolia</i> Heyne (Campanulaceae).	
	Vernacular names: Nala, Dawal, Kuttuppugaiyilai.	
	8. <i>Polygala Chinensis</i> Linn. (Polygalaceae.)	Chanda, Khandwa Dist.
	Vernacular name: Meradu.	
	9. <i>Punica granatum</i> Linn. (Lythraceae).	Jubbulpore.
	Vernacular names: Dalimgachh, Dalimba, Anar, Madulam.	
	10. <i>Santalum album</i> Linn. (Santalaceae).	Nimar Dist., Saugor Dist.
	Vernacular names: Chandan, Ingam.	
	11. <i>Acacia catechu</i> Willd. (Leguminosae).	Bilaspur forests, Chanda North, Damoh Forest Division, Jub- bulpore Forest Division, Raipur Forest, Saugor Forest Divi- sion.
	Vernacular names: Kuth, Khai- ra, Khair, Karungali.	

1	2	3
<b>MADRAS.</b>	<p>1. <i>Acacia Arabica</i> Willd. (Leguminosae). Vernacular names: Babul, Kikar, Karuvel.</p> <p>2. <i>Arachis hypogaea</i> Linn (Leguminosae). Vernacular names: Chiner badam, Bhuimuga, Mungphali, Nilakkadalai.</p> <p>3. <i>Capsicum minimum</i> Roxb. (Solanaceae). Vernacular names: Lanka morich, Gach marich, Peymilagay.</p> <p>4. <i>Cassia angustifolia</i> Vahl (Leguminosae). Vernacular names: Sonpat, Hindi Sana, Nila Virai.</p> <p>5. <i>Cassia fistula</i> Linn. (Leguminosae). Vernacular names: Sonali, Amaltas, Aragoram.</p> <p>6. <i>Chenopodium album</i> Linn (Chenopodiaceae). Vernacular names: Bathusag, Chakwit, Parupukkirai.</p> <p>7. <i>Cinchona Ledgeriana</i> Moens (Rubiaceae). (B.P. 1932).</p> <p>8. <i>Cinchona officinalis</i> Linn. (Rubiaceae). (B.P. 1932).</p> <p>9. <i>Cinchona Succirubra</i> Pavon (Rubiaceae). (B.P. 1932).</p> <p>10. <i>Cinnamomum Camphora</i> Nees and Eberm. (Lauraceae). Vernacular names: Karpur, Kapur, Karppuram.</p> <p>11. <i>Cinnamomum Zeylanicum</i> Nees (Lauraceae). Vernacular names: Dalchini, Ilavangam.</p> <p>12. <i>Citrullus Colocynthis</i> Schrad (Cucurbitaceae). Vernacular names: Makhal, Indrayan, Peykumutti.</p> <p>13. <i>Citrus aurantium</i> Linn (Rutaceae). Vernacular names: Kamla nembu, Narangi, Sangtara, Narangam.</p> <p>14. <i>Citrus medica</i> Linn. Var. Limonum Linn. (Rutaceae).</p>	<p>Chittor, Coimbatore, Madras, Cuddapah, Guntur Dist.</p> <p>Central Districts of Chittor, North &amp; South Arcot, Salem, Trichinopoly, Coimbatore, Cuddapah, Kurnool, Bellary &amp; Anantpur &amp; the Circars districts of Vizagapatam, E. &amp; W. Godavari, Kistna, Guntur.</p> <p>Borders of fields in South India.</p> <p>Madura Dist., Tinnevely.</p> <p>Nilgiri Dist., Coimbatore Dist., Madura Dist., Shevaroy Hills, Salem Dist.</p> <p>Madras, Malabar, Madura Dist.</p> <p>Naduvattam plantations.</p> <p>Nilgiris.</p> <p>Nilgiris &amp; Naduvattam plantations.</p> <p>Nilgiri Hills.</p> <p>Malabar Dist., Nilgiris, Coimbatore Dist., South Kanara Dist., Nilgiri Dist.</p> <p>Madura Dist., Anantapur Dist., Madras, Nellore Dist., Tinnevely Dist.</p> <p>Madras State (Guntur.)</p> <p>Madras State.</p>

1	2	3
MADRAS— <i>contd.</i>	Vernacular names: Bara nebu, Bara nimbu, Gulgul, Madu- lam.	
	15. <i>Claviceps purpurea</i> Tulas- ne (Hypocreaceae).	Nilgiris.
	16. <i>Digitalis purpurea</i> Linn. (Scrophulariaceae).	Madura Dist., Nilgiri Dist.
	17. <i>Elettaria Cardamomum</i> Moton Var. <i>Minuscula</i> Bur- kill (Zingiberaceae).	Malabar Dist., South Kanara Dist., Madura Dist., Tinnevely Dist., Nilgiri Dist., Salem Dist.
	Vernacular names: Elachi, Ilachi, Chotti Elachi, Ilanji.	
	18. <i>Erythroxylum Coca</i> lam. (Erythroxylaceae).	Nilgiris.
	Vernacular name : Sivadari.	
	19. <i>Eucalyptus globulus</i> Labill (Myrtaceae).	Nilgiri Dist.
	Vernacular name: Karupura- maram.	
	20. <i>Hydnocarpus Wightiana</i> Blume (Bixaceae).	South Malabar Dist., Madura Dist., Anamalai Hills, Coimba- tore Dist.
	Vernacular names: Chaulmugra, Kauti, Garudaphala, Mara- vetti.	
	21. <i>Ipomoea purga</i> Hayne (Con- volvulaceae). (B. P. 1932).	Nilgiri Hills.
	22. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae).	Adyar, Malabar, Mount Nilgir Coimbatore Dist.
	Vernacular names: Dhudkalmi, Nishotar, Pithori, Kumbam.	
	23. <i>Lobelia nicotianifolia</i> Hey- ne. (Campanulaceae).	Coimbatore Dist., Malabar Dist. Tinnevely Dist., Madura Dist., Mount Nilgiri, Nilgiris, Shem- barganur, Pulneys.
	Vernacular names: Nala, Dawal, Kuttupugaiyilai.	
	24. <i>Mentha piperita</i> Linn. (Labiatae).	Nilgiris.
	25. <i>Myristica fragrans</i> Houtt. (Myristicaceae).	Govt. Gardens at Burliar.
	Vernacular names: Jayphal, Jaiphal, Sidam.	
	26. <i>Polygala Chinensis</i> Linn. (Polygalaceae).	Bellary, Coimbatore Dist., Chin- gleput Dist., Cuddapah Dist. Ganjam Dist., Nilgiri Dist., Madras, Godavari Dist., Salem Dist., Malabar Dist.
	Vernacular name: Meradu.	
	27. <i>Punica granatum</i> Linn. (Lythraceae).	Salem Dist.
	Vernacular names: Dalimgacnh, Dalimba, Anar, Madulam.	
	28. <i>Ricinus communis</i> Linn. (Euphorbiaceae).	Anantpur, Bellary, Coimbatore, Cuddapah, Kurnool, Kistna, Madras, Nellore.
	Vernacular names: Bherenda, Erendi, Arend, Attagam.	

1	2	3
<b>MADRAS—</b> <i>contd.</i>	29. <i>Santalum album</i> Linn. (Santalaceae). Vernacular names: Chandan, Ingam.	North Arcot Dist., Nilgiri Dist., Cuddapah Dist., Salem Dist., Madras, Madura, Tinne- velly Dist., South Arcot Dist., Sandur (State).
	30. <i>Strychnos nux-vomica</i> Linn. (Loganiaceae). Vernacular names: Kuchila, Kara, Kuchla, Karalam.	Anamalai Hills, Karnool Dist. North Kanara Dist., Godavari, Dist., Nellore Dist., Kistna Dist. Madras Dist., North Arcot Dist., South Kanara Dist.
	31. <i>Tamarindus indica</i> Linn. (Leguminosae). Vernacular names: Tentul, Amli, Imli, Amilam.	Coimbatore, Madras, Nellore Dist.
	32. <i>Theobroma cacao</i> Linn. (Sterculiaceae).	Nilgiris, Malabar Coast, Tinne- velly.
	33. <i>Acacia catachu</i> Willd. (Le- guminosae). Vernacular names: Kuth, Khaira, Khair, Karungali.	Coimbatore Dist., Vizagapatam Dist., Malabar South, North Circars.
	34. <i>Urginea indica</i> Kunth (Liliaceae). Vernacular names: Ban piaz, Jangli piaz, Narivengayam.	Anamalai Hills, Coimbatore Dist.
<b>ORISSA.</b>	1. <i>Cassia fistula</i> Linn. (Le- guminosae). (B.P. 1932). Vernacular names: Sonali, Amal- tas, Aragoram.	Ganjam Dist.
	2. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae). Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.	Angul.
	3. <i>Pimpinella anisum</i> Linn. (Umbelliferae). Vernacular names: Muhuri, Sonf, Shombu.	Orissa State.
	4. <i>Ricinus communis</i> Linn. (Euphorbiaceae). Vernacular names: Bherenda, Erendi, Arend, Attagam.	Cuttack.
	5. <i>Strychnos nux-vomica</i> Linn. (Loganiaceae). Vernacular names: Kuchila, Kara, Kuchla, Karalam.	Ganjam Dist., Cuttack.
	6. <i>Acacia catechu</i> Willd. (Le- guminosae). Vernacular names: Kuth, Khai- ra, Khair, Karungali.	Angul, Ganjam Dist.
	7. <i>Urginea Indica</i> Kunth. (Liliaceae). Vernacular names: Ban piaz, Jangli piaz, Narivengayam.	Angul.

1	2	3
PUNJAB & HIMACHAL PRADESH	1. <i>Acacia Senegal</i> Willd. (Leguminosae).	Rohtak.
	Vernacular names: Kumta, Sveta, Khadira, Khor.	
	2. <i>Acacia Arabica</i> Willd. (Leguminosae).	Amritsar.
	Vernacular names: Babue, Ki- kar, Karuvel.	
	3. <i>Aloe barbadensis</i> Mill. (Liliaceae).	Amritsar, Ludhiana.
	Vernacular names: Ghirta- kumari, Ghi-kavar, Kattalai.	
	4. <i>Anethum graveolens</i> Linn. (Umbelliferae).	Amritsar.
	Vernacular names: Shulpa, Soya.	
	5. <i>Astragalus Strobiliferus</i> Royle (Compositae).	Kangra Dist.
	Vernacular name: Kon.	
	6. <i>Camellia Sinensis</i> Linn. O. Kuntze. (Theaceae).	Kangra Dist., Hoshiarpur Dis
	Vernacular name: Cha.	
	7. <i>Carum Carvi</i> Linn. (Um- belliferae).	Kangra Dist.
	Vernacular names: Jira, Vilayati Zirah, Zira, Simaishembu.	
	8. <i>Cassia Fistula</i> Linn. (Le- guminosae). (B.P. 1932).	Gurdaspur Dist., Hoshiarpur.
	Vernacular names: Sonali, Amaltas, Aragoram.	
	9. <i>Chenopodium album</i> Linn. (Chenopodiaceae).	Amritsar, Kangra Dist., Simla.
	Vernacular names: Bathusag, Chakwit, Parupukkirai.	
	10. <i>Citrullus Colocynthis</i> Sch- rad (Cucurbitaceae).	Jullundur, Simla Hills.
	Vernacular names: Makhal, Ind- rayan, Peykumutti.	
	11. (a) <i>Datura Stramonium</i> Linn. (Solanaceae).	Chamba State, Bashahr State
	(b) <i>Datura tatula</i> Linn. (Solanaceae).	Simla.
	Vernacular names: Sada dhu- tura, Dhattura, Umattaka.	
	12. <i>Ephebra geradisna</i> Wall. (including <i>E. nebrodensis</i> Tineo). (Gnetaceae).	Kangra Dist., Chamba State, Bhaji State, Simla Dist.
	Vernacular names: Tutgantha, Asmania.	
	13. <i>Eucalyptus globulus</i> La- bill. (Myrtaceae).	Kangra Dist.
	Vernacular name: Karupu- ramaram.	



1	2	3
PUNJAB & HIMACHAL PRADESH— <i>contd.</i>	14. <i>Picrorhiza Kurroa</i> Royle (Scrophulariaceae). Vernacular names: Katki, Kali Katki, Kuru, Katukurogani.	Kangra Dist., Chamba State.
	15. <i>Hyoscyamus niger</i> Linn. (Solanaceae). Vernacular names: Khorasani ajowan, Khorasani owa, Kurasani-ajvayan, Kurasani yomam.	Chamba State, Bashahr State, Simla Dist., Kangra Dist.
	16. <i>Linum Usitatissimum</i> Linn. (Linaceae). (B.P. 1932). Vernacular names: Tisi, Alasi, Alsi, Alshi.	Ambala, Gurdaspur, Hoshiarpur, Kangra, Simla.
	17. <i>Papaver Somniferum</i> Linn. (Papaveraceae). Vernacular names: Post, Afim, Postuka.	Ambala, Chamba, Gurgaon, Hoshiarpur, Jullundur, Kangra Dist., Ludhiana, Simla.
	18. <i>Picraena quassioides</i> Benth. (Simarubaceae). Vernacular names: Bhurungi, Bharangi, Bering.	Chamba, Simla Dist., Kangra Dist.
	19. <i>Pimpinella anisum</i> Linn. (Umbelliferae). Vernacular names: Muhuri, Sonf, Shombu.	Certain parts of the State.
	20. <i>Pinus Longifolia</i> Linn. (Coniferae). Vernacular names: Saralagach, Chil, Simaidevadari.	Chamba, Hoshiarpur, Kangra Dist., Kasauli, Simla.
	21. <i>Podophyllum emodi</i> Wall. (Berberidaceae). Vernacular names: Papra, Ban- wangan, Ban Kakri.	Chamba State, Bashahr State, Kangra Dist., Simla Dist.
	22. <i>Polygala Chinensis</i> Linn. (Polygalaceae). Vernacular name: Meradu.	Chamba State, Gurdaspur Dist., Kangra Dist., Simla Hills.
	23. <i>Prunus amygdalus</i> Batsch Var. <i>dulcis</i> . (D.C.) Koehne. or <i>Prunus amygdalus</i> Batsch. Var. <i>amara</i> (D.C.) Focke. (Rosaceae). Vernacular names: Bilati badam, Badam, Vadumai.	Punjab State.
	24. <i>Punica granatum</i> Linn. (Lythraceae). Vernacular names: Dalimgachh, Dalimba, Anar, Madulam.	Amritsar, Chamba State, Gur- daspur, Hoshiarpur, Kangra Dist., Simla.
	25. <i>Rheum emodi</i> Wall. (Poly- gonaceae). Vernacular names: Banglarevan- chi, Ladakirevandachini, Hindi revandchini, Nattire- valechinni.	Bashahr State, Simla Hills, Kangra Dist., Parbatti Valley.

1	2	3
PUNJAB & HIMACHAL PRADESH — <i>comd.</i>	26. <i>Rheum Webbianum</i> Royle. (Polygonaceae). Vernacular names: Archu, Lachu, Padamchal.	Bashahr State, Simla Hills, Chamba State.
	27. <i>Ricinus Communis</i> Linn. (Euphorbiaceae). Vernacular names: Bherenda, Brendi, Arend, Attagam.	Ambala, Hoshiarpur.
	28. <i>Salix fragilis</i> Linn. (Salicaceae).	Kangra Dist., Chamba State..
	29. <i>Tamarindus indica</i> Linn. (Leguminosae) Vernacular names: Tentul, Amli, Imli, Amilam.	Amritsar, Hoshiarpur.
	30. <i>Acacia Catechu</i> Willd. (Leguminosae). Vernacular names: Kuth, Khaira, Khair, Karungali.	Hoshiarpur Kangra.
	31. <i>Urginea indica</i> Kunth (Liliaceae). Vernacular names: Ban piaz, Jangli piaz, Narivengayam.	Simla.
	32. <i>Valeriana Wallichii</i> DC. (Valerianaceae). Vernacular names: Mushkbala, Tagara.	Chamba, Kangra Dist. Simla Hills.
UTTAR PRADESH.	1. <i>Acacia arabica</i> Willd. (Leguminosae). Vernacular names: Babul, Ki- kar, Karuvel.	Bharatpur, Kheri, Saharanpur, Dehra Dun.
	2. <i>Aloe barbadensis</i> Mill. (Liliaceae). Vernacular names: Ghirtaku- mari, Ghi-kavar, Kattalai.	Dehra Dun gardens.
	3. <i>Anethum graveolens</i> Linn. (Umbelliferae). Vernacular names: Shulpa, Soya.	Banda, Gonda Dist., Lucknow Saharanpur.
	4. <i>Camellia Sinensis</i> Linn. O. Kuntze (Theaceae). Vernacular name: Cha.	Dehra Dun Dist., Garhwal Dist. Kumaon.
	5. <i>Garum Carvi</i> Linn. (Umbelliferae). Vernacular names: Jira, Vilayati, Zirah, Zira, Simaishembu.	Tehri Garhwal, Almora Dist.
	6. <i>Cassia Fistula</i> Linn. (Leguminosae). Vernacular names: Sonali, Amaltas, Aragoram.	Garhwal Dist., Dehra Dun Dist., Gorakhpur Dist., Naini Tal Dist., Gonda Dist.
	7. <i>Chenopodium album</i> Linn. (Chenopodiaceae). Vernacular names: Bathusag, Chakwit, Parupukkirai.	Etawah, Siwaliks, Allahabad Gonda Dist., Banda, Kheri Dist., Tehri Garhwal, Dehra Dun Dist., Mussorie, Naini Tal, Saharanpur, Gorakhpur, Chakrata range.

I	2	3
UTTAR PRADESH— contd.	8. <i>Cinnamomum</i> Camphore Nees and Eberm. (Lauraceae). Vernacular names: Karpur, Kapur, Karppuram.	Dehra Dun (Forest School Garden) and (Khandhuli gar- dens), Saharanpur.
	9. <i>Cinnamomum</i> Zeylanicum Nees (Lauraceae). Vernacular names: Dalchini, Ilavangam.	Dehra Dun.
	10. <i>Citrullus Colocynthis</i> Sch- rad. (Cucurbitaceae). Vernacular names: Makhal, Indrayan, Peykumutti.	Saharanpur garden.
	11. <i>Citrus medica</i> Linn. Var. Limonum, Linn. (Rutaceae) Vernacular names: Bara nebu, Bara nimbu, Gulgul, Madulam.	Almora and other parts of the State.
	12. (a) <i>Datura Stramonium</i> Linn. (Solanaceae) (b) <i>Datura tatula</i> Linn. (Solanaceae) Vernacular names: Sada dhu- tura, Dhattura, Umattaka.	Naini Tal, Almora Dist.
	13. <i>Digitalis purpurea</i> Linn. (Scrophulariaceae)	Almora Dist.
	14. <i>Ephebra gerardisna</i> Wall (Including <i>E. Nebrodensis</i> Tineo) (Gnetaceae). Vernacular names: Tutgantha, Asmania.	Garhwal Dist., Almora Dist. Jaunsar, Kumaon, Tehri Garh- wal.
	15. <i>Eucalyptus globulus</i> La- bill. (Myrtaceae). Vernacular name: Karupurama- ram.	Dalmoti, Dehru Dun, Almora, Saharanpur Botanical garden.
	16. <i>Picrorhiza Kurroa</i> Royle. (Scrophulariaceae). Vernacular names: Katki, Kali Katki, Kuru, Katukurogani.	Garhwal Dist., Theri Garhwal, Mussoorie, Almora Dist., Ku- maon.
	17. <i>Hydnocarpus Wightiana</i> Blume. (Bixaceae). Vernacular names: Chaulmugra, Kauti, Garudaphala, Mara- vetti.	Dehra Dun Forest Research Institute.
	18. <i>Hyoscyamus niger</i> Linn. (Solanaceae). Vernacular names: Khorasani ajowan, Khorasani owa, Khurasani-ajvayan, Kurasani yomam.	Kumaon, Saharanpur.
	19. <i>Ipomoea purga</i> Hayne (Convolvulaceae). (B. P. 1932).	Mussoorie.

1	2	3
UTTAR PRA- DESH—Contd.	20. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae). Vernacular names: Dhudkal- mi, nishotar, pitohri, Kum- bam.	Banda, Dehra Dun, Kheri Dist., Moradabad.
	21. <i>Linum Usitatissimum</i> Linn. (Linaceae). (B.P. 1932). Vernacular names: Tisi, Alasi, Alsi, Alshi,	Allahabad, Azamgarh, Banda, Basti, Benaras Div., Dehra Dun, Gorakhpur, Hamirpur, Jharosi, Jalaun, Kumaon, Lalitpur, Mirzapur, Morada- bad, Saharanapur.
	22. <i>Lobelia Nicotianifolia</i> Hey- ne. (Campanulaceae). Vernacular names: Nala, Dawal, Kuttupugaiylai.	Dehra Dun.
	23. <i>Papaver Somniferum</i> Linn. (Papaveraceae). Vernacular names: Post, Afim, Postaka.	Aligarh, Allahabad, Azimgarh, Basti, Dehra Dun, Faizabad, Etawah, Farukhabad, Fateh- garh, Gazipur, Gonda, Gora- khpur, Jalaun, Lucknow, Mir- zapur, Partapgarh, Rai Bareilly, Shajahanpur, Sitapur, Sultan- pur.
	24. <i>Picraena quassioides</i> Benth. (Simarubaceae). Vernacular names: Bhurungi, Bharangi, Bering.	Bamsu Reserve, Dehra Dun Dist., Garhwal, Mussoorie, Tehri Garhwal.
	25. <i>Pimpinella anisum</i> Linn. (Umbelliferae). Vernacular names: Muhuri, Sonf, Shombu.	Certain parts of the States.
	26. <i>Pinus Longifolia</i> Linn. (Coniferae). Vernacular names: Saralagach, Chil, Simaidevadari.	Allahabad (cult.) Jaunsar, Garh- wal Dist., Dehra Dun., Naini Tal Dist., Almora Dist.
	27. <i>Podophyllum emodi</i> Wall. (Berberidaceae). Vernacular names: Papra, Ban- wangan, Ban kakri.	Dehra Dun Dist., Garhwal Dist., Tehri Garhwal State, Almora Dist.
	28. <i>Polygala Chinensis</i> Linn. (Polygalaceae). Vernacular name: Meradu.	Agra, Allahabad, Almora, Ban- da, Dehra Dun, Tehri Garh- wal, Hamirpur, Jalaun, Jhansi, Moradabad.
	29. <i>Punica granatum</i> Linn. (Lythraceae). Vernacular names: Dalimgachh, Dalimba, Anar, Madulam.	Almora, Dehra Dun Dist., Kheri Dist., Laluri, Tehri Garhwal, Mussoorie.
	30. <i>Rheum emodi</i> Wall. (Poly- gonaceae). Vernacular names: Banglarevan- chi, Ladakirevandachini, Hin- di revandchini, Nattirevale- chinni.	Tehri Garhwal, Dehra Dun Dist.

1	2	3
UTTAR PRA- DESH—Contd.	<p>31. <i>Rheum Webbianum</i> Royle. (Polygonaceae). Vernacular names: Archu, Lachu, Padamchal.</p> <p>32. <i>Ricinus Communis</i> Linn. (Euphorbiaceae). Vernacular names: Bherenda, Erendi, Arend, Attagam.</p> <p>33. <i>Santalum album</i> Linn. (Santalaceae). Vernacular names: Chandan, Ingam.</p> <p>34. <i>Strychnos nux-vomica</i> Linn. (Loganiaceae). Vernacular names: Kuchila, Kara, Kuchla, Karalam.</p> <p>35. <i>Trachyspermum ammi</i> (Linn). Sprague (Umbelliferae). Vernacular names: Jowan, Ajwan, Ajwain, Amam.</p> <p>36. <i>Acacia Catechu</i> Willd. (Leguminosae). Vernacular names: Kuth, Khaira, Khair, Karungali.</p> <p>37. <i>Urginea indica</i> Kunth. (Liliaceae). Vernacular names: Ban piaz, Jangli piaz, Narivengayam.</p> <p>38. <i>Valeriana Wallichii</i> DC. (Valerianaceae). Vernacular names: Muskhbala, Tagara.</p>	<p>Almora Dist.</p> <p>Allahabad, Banda, Dehra Dun, New Forest, Naini Tal Dist., Kheri Dist., Moradabad.</p> <p>Kheri Dist., Dehra Dun.</p> <p>Gorakhpur, Lucknow, Saharanpur Botanic gardens, Surajbagh experimental farm, Dehra Dun.</p> <p>Banda, Dehra Dun, Fatehgarh, Farrukhabad Dist.</p> <p>Garhwal Dist., Aghar valley—Mussoorie, Bahraich, Banda, Naini Tal Dist., Dehra Dun, Gonda, Gorakhpur, Jalaun Dist., Saharanpur Siwaliks, Kumaon.</p> <p>Almora, Garhwal, Jhansi Divn., Pilibhit Sub-Himalayan tract, Gonda Dist., Tehri Garhwal, Pindar Valley.</p> <p>Tehri, Garhwal, Dehra Dun Dist., Garhwal, Almora Dist., Mussoorie, Kermi-falls, Naini Tal.</p>
WEST BENGAL	<p>1. <i>Acacia Arabica</i> Willd. (Leguminosae). Vernacular names: Babul, Kikar, Karunel.</p> <p>2. <i>Anethum graveolens</i> Linn. (Umbelliferae). Vernacular names: Shulpha, Soya.</p> <p>3. <i>Camellia Sinensis</i> Linn. O. Kuntze. (Theaceae). Vernacular name: Cha.</p> <p>4. <i>Capsicum minimum</i> Roxb. (Solanaceae). Vernacular names: Lanka morich, Gach marich, Peyimlagay.</p> <p>5. <i>Carum Carvi</i> Linn. (Umbelliferae).</p>	<p>Sibpur Royal Botanic Garden, Calcutta.</p> <p>Sibpur Royal Botanic Garden, Calcutta.</p> <p>Pashak Estate, Darjeeling Dist.</p> <p>Bengal—borders of fields.</p> <p>Darjeeling.</p>

WEST BEN- GAL—Contd.	Vernacular names: Jira, Vilayati Zirah, Zira, Simaishembu.	
6.	<i>Cassia fistula</i> Linn. (Leguminosae). (B.P. 1932).	Chandernagore and Sibpur, Calcutta, Darjeeling.
	Vernacular names: Sonali, Amaltas, Aragoram.	
7.	<i>Cephaelis ipecacuanha</i> (Brot.) A. Rich (Rubiaceae).	Mungpoo, Darjeeling Dist.
8.	<i>Chenopodium album</i> Linn. (Chenopodiaceae).	Manikgunj, Jalpaiguri, Nawabganj, Sibpur.
	Vernacular names: Bathusag, Chakwit, Parupukkirai.	
9.	<i>Cinchona Ledgeriana</i> Moens. (B.P. 1932). (Rubiaceae).	Government of Bengal Plantations.
10.	<i>Cinchona Succirubra</i> Pavon (Rubiaceae). (B. P. 1932).	Mungpoo Plantations.
11.	<i>Cinnamomum Camphora</i> Nees and Eberm (Lauraceae).	Sibpur Royal Botanic Garden, Calcutta.
	Vernacular names: Karpur, Kapur, Karppuram.	
12.	<i>Cinnamomum Zeylanicum</i> Nees. (Lauraceae).	Sibpur near Calcutta.
	Vernacular names: Dalchini, Ilavangam.	
13.	<i>Citrullus Colocynthis</i> Schrad. (Cucurbitaceae).	Sibpur near Calcutta.
	Vernacular names: Makhal, Indrayan, Peykumutti.	
14.	(a) <i>Datura Stramonium</i> Linn. (Solanaceae).	Darjeeling Dist.
	(b) <i>Datura tatula</i> Linn. (Solanaceae).	
	Vernacular names: Sada dhutura, Dhattura, Umattaka.	
15.	<i>Digitalis purpurea</i> Linn. (Scrophulariaceae).	Darjeeling.
16.	<i>Erythroxylum coca</i> Lam. (Erythroxylaceae).	Sibpur Royal Botanic Garden, near Calcutta.
	Vernacular name: Sivadari.	
17.	<i>Eucalyptus globulus</i> Labill. (Myrtaceae).	Rangbi Tea Estate and Rangyrum Estate in Darjeeling Dist.
	Vernacular name: Karupuramaram.	
18.	<i>Hydnocarpus Wightiana</i> Blume. (Bixaceae).	Sibpur Royal Botanic Garden, Calcutta.
	Vernacular names: Chaulmugra, Kauti, Garudaphala, Maravetti.	
19.	<i>Ipomoea turpethum</i> R. Br. (Convolvulaceae).	Hooghly, Sibpur-Calcutta.

1	2	3
WEST BENGAL— <i>Conid.</i>	Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.	
	20. <i>Linum usitatissimum</i> Linn. (Linaceae). (B.P. 1932.)	Burdwan, Jessore, Murshidabad, Nadia.
	Vernacular names: Tisi, Alasi, Alsi, Alshi.	
	21. <i>Pinus Longifolia</i> Linn. (Coniferae).	Darjeeling Dist.
	Vernacular names: Saralagach, Chil, Simaidevadari.	
	22. <i>Ricinus Communis</i> Linn. (Euphorbiaceae).	Jessore, Nadia, Sibpur Calcutta.
	Vernacular names: Bherenda, Erendi, Arend, Attagam.	
	23. <i>Santalum album</i> Linn. (Santalaceae).	Sibpur Royal Botanic Garden, Calcutta.
	Vernacular names: Chandan, Ingam.	
	24. <i>Strychnos nux—Vomica</i> Linn. (Loganiaceae).	Sibpur Royal Botanic Garden, Calcutta.
	Vernacular names: Kuchila, Kara, Kuchla, Karalam.	
	25. <i>Trachyspermum ammi</i> (Linn.) Sprague (Umbelliferae).	Sibpur Royal Botanic Garden, Calcutta, 24 Parganas.
	Vernacular names: Jowan, Ajwan, Ajwain, Amam.	
	26. <i>Acacia Catechu</i> Willd. (Leguminosae).	Darjeeling Dist., Sibpur Botanic Garden, Calcutta.
	Vernacular names: Kuth, Khaira, Khair, Karungali.	
	27. <i>Urginea indica</i> Kunth (Liliaceae).	Sibpur Royal Botanic Garden, Calcutta.
	Vernacular names: Ban piaz, Jangli piaz, Narivengayam.	
	28. <i>Valeriana Wallichii</i> DC. (Valerianaceae).	Darjeeling Dist.
	Vernacular names: Mushkbala, Tagara.	
JAMMU & KASHMIR	1. <i>Acacia arabica</i> Willd. (Leguminosae).	Jammu, Mirpur, Muzaffarabad, Udhampur.
	Vernacular names: Babul, Kikar, Karuvel.	
	2. <i>Aconitum Chasmanthum</i> Stapfex Holmes. (Ranunculaceae).	Baramula, Burzil, Butta-sums, Darlah, Sonemarg, Gulmarg, Gurez, Gilgit Wazrat, Kazinag, Khillanmarg, Kosarnag, Kamri, Valley, Hichnai pass, Tilel Hills and Valley Vanjan.
	Vernacular names: Mohri Bانبalnag.	Muzaffarabad.
	3. <i>Aloe barbadensis</i> Mill. (Liliaceae).	
	Vernacular names: Ghirtakumari, Ghikavar, Kattalai.	

1	2	3
JAMMU & KASHMIR— <i>cont'd.</i>	<p>4. <i>Artemisia brevifoli</i> Wall. (Compositae). Vernacular names: Kirmala, Murni.</p> <p>5. <i>Artemisia maritima</i> Linn. forma <i>rubricaula</i> Badhwar. (Compositae). Vernacular names: Kirmala, Murni.</p> <p>6. <i>Astragalus Strobiliferus</i> Royle. (Compositae). Vernacular name: Kon.</p> <p>7. <i>Atropa acuminata</i> Royle ex Lindley. (Solanaceae). Vernacular names: Yebruj, Girbuti, Angur Shefa, Mait brand.</p> <p>8. <i>Atropa belladonna</i> Linn. (Solanaceae). Vernacular names: Yebruj, Girbuti, Angur Shefa, Mait brand.</p> <p>9. <i>Carum Carvi</i> Linn. (Umbelliferae). Vernacular names: Jira, Vilayati Zirah, Zira, Simaishembu.</p> <p>10. <i>Cassia Fistula</i> Linn. (Leguminosae). (B. P. 1932.) Vernacular names: Sonali, Amaltas, Aragoram.</p> <p>11. <i>Chenopodium album</i> Linn. (Chenopodiaceae). Vernacular names: Bathusag, Chakwit, Parupukkirai.</p> <p>12. <i>Colchicum luteum</i> Baker. (Liliaceae). Vernacular names: Hiranutiya, Surajane talkh.</p> <p>13. <i>Digitalis purpurea</i> Linn. (Scrophulariaceae).</p> <p>14. <i>Ephedra gerardiana</i> Wall. (including <i>E. nebrodensis</i> Tineo) (Conotaceae). Vernacular names: Tutgantha, Asmania.</p> <p>15. <i>Ferula narthex</i> Boiss (Umbelliferae). Vernacular names: Hing, Perungayam.</p> <p>16. <i>Picrorhiza Kurroa</i> Royle (Scrophulariaceae).</p>	<p>Astore, Balistan, Gilgit, Gurez, Jelaun, Chanab Valley, Rattu, Telil, Sind Forest Division.</p> <p>Kashmir to Kumaon.</p> <p>Astore, Gudai Konum, Kunawar</p> <p>Badharwah division, Gulmarg, Jagran river banks, Kamraj, Kishenganga valley, Kishtwar, Kunawar, Langet, Lolab valley forest Muzaffarabad, Pir Panjal, Rajwar forests, Sind valley.</p> <p>Baramula, Darrang, Yarikah nurseries.</p> <p>Astore, Sind Valley, Bhagbanpura, Gurez, Baltistan, Ladakh Skardu.</p> <p>Jammu, Mirpur, Nowshera, Reasi, Udhampur.</p> <p>Dras Valley, Baltistan.</p> <p>Badharwah, Baramula, Chenab Valley, Domel, Garhi, Gulmarg, Kishtawar, Sonemarg, Sind Valley, Srinagar.</p> <p>Kairu forests and Yarikah in Tangmarg.</p> <p>Kishenganga Valley, Sind Valley, Baltistan, West of Dras, Jhelum Valley, Zaakar, Ladakh, Naltar Valley, North of Gilgit, Rupshu, Srinagar.</p> <p>Astore, Baltistan, Chenab Valley.</p> <p>Burzil pass, Gurez pass, Kamasri pass. Gurez. Kolanhoi.</p>



1	2	3
<b>JAMMU &amp; KASHMIR</b> —contd.	Vernacular names: Katki, Kali Katki, Kuru, Katukurogani.	Ladakh, Lidder Valley, Pir Panjal, Zaskar, Traghah, Zojipal.
	17. <i>Glycyrrhiza glabra</i> Linn. (Leguminosae).	Baramula nursery.
	Vernacular names: Jashti 'madhu, Mulathi, Atimaduram.	
	18. <i>Hyoscyamus niger</i> Linn. (Solanaceae).	Baramula, Darrang, Dras, Gulmarg, Muzaffarabad, Anantnag, Korakaram range, Ladakh, Pahalgam, Sind valley, Shopyan range, Srinagar, Yarikah.
	Vernacular names: Khorasani ajowan, Khorasani owa, Khurasani ajvayan, Kurasani yomam.	
	19. <i>Lavandula officinalis</i> Chaix (Labiatae).	Chattarnar and Srinagar nurseries
	20. <i>Mentha piperita</i> Linn. (Labiatae).	Baramula nursery.
	21. <i>Papaver Somniferum</i> Linn. (Papaveraceae).	Doda, Kishtwar, Srinagar.
	Vernacular names: Post, Afim, Postaka.	
	22. <i>Pinus Longifolia</i> Linn. (Coniferae).	Kathua, Kotli, Mirpur, Muzaffarabad, Ramnagar, Reasi,
	Vernacular names: Saralgach, Chil, Simaidevadari.	Udhampur.
	23. <i>Podophyllum emodi</i> Wall. (Berberidaceae).	Daitwas forest, Gilgit, Gulmarg, Kishenganga valley, Jhelum basin, Khelanmarg, Lidwas, Sind valley, Tangmarg forest, Zaskar, Zoji la.
	Vernacular names: Papra, Banwangan, Bankakri.	
	24. <i>Prunus amygdalus</i> Batsch Var. <i>dulcis</i> (D.C.) Koehne.	Kashmir State.
	or <i>Prunus amygdalus</i> Batsch Var. <i>amara</i> (D.C.) Focke.	
	Vernacular names: Bilati badam, Badam, Vadumai.	
	25. <i>Punica granatum</i> Linn. (Lythraceae).	Tawi valley, Jammu, Kishenganga valley, Poonch, Srinagar
	Vernacular names: Dalimgachh, Dalimba, Anar, Madulam.	
	26. <i>Rheum emodi</i> Wall. (Polygonaceae).	Ladakh, Kashmir North, Gulmarg, Jhelum valley, Kamri Khelanmarg, Sind valley.
	Vernacular names: Banglarevanchi, Ladakirevandachini, Hindi revandchini, Nattirevachinni.	
	27. <i>Rheum Webbianum</i> Royle. (Polygonaceae).	Burzil.
	Vernacular names: Archu, Lachu, Padamchal.	
	28. <i>Ricinus Communis</i> Linn. (Euphorbiaceae).	Jammu, Kishenganga valley.

1	2	3
JAMMU & KASHMIR —contd.	<p>Vernacular names: Bherenda, Brendi, Arend, Attagam.</p> <p>29. <i>Salix Fragilis</i> Linn. (Salicaceae).</p> <p>30. <i>Acacia Catechu</i> Willd (Leguminosae).</p> <p>Vernacular names: Kuth, Khaira, Khair, Karungali.</p> <p>31. <i>Valeriana Wallichii</i> DC. (Valerianaceae).</p> <p>Vernacular names: Mushkbala, Tagara.</p>	<p>Ladakh.</p> <p>Billawar, Jammu,</p> <p>Sind valley, Deo Masjid valley, Dras, Lidder valley, Zebanwan mountain.</p>
HYDERABAD.	<p>1. <i>Arachis hypogaea</i> Linn. (Leguminosae).</p> <p>Vernacular names: Chinar badam, Bhui muga, Mungphali, Nilakkadalai.</p> <p>2. <i>Trachyspermum ammi</i> (Linn.) Sprague. (Umbelliferae).</p> <p>Vernacular names: Jowan, Ajwan, Ajwain, Amam.</p>	<p>Gulbarga, Osmanabad, Raichur, Mahboob nagar,</p> <p>Hyderabad State.</p>
MADHYA BHARAT & BHOPAL.	<p>1. <i>Cassia fistula</i> Linn. (Leguminosae). (B. P. 1932.)</p> <p>Vernacular names: Sonali, Amaltas, Aragoram.</p> <p>2. <i>Papaver Somniferum</i> Linn. (Papaveraceae).</p> <p>Vernacular names: Post, Afim, Postaka.</p> <p>3. <i>Tamarindus Indica</i> Linn. (Leguminosae).</p> <p>Vernacular names: Tentul, Amli, Imli, Amilam.</p> <p>4. <i>Trachyspermum ammi</i> (Linn) Sprague. (Umbelliferae).</p> <p>Vernacular names: Jowan, Ajwan, Ajwain, Amam.</p> <p>5. <i>Acacia Catechu</i> Willd. (Leguminosae).</p> <p>Vernacular names: Kuth, Khaira, Khair, Karungali.</p>	<p>Isagarh District.</p> <p>Bhopal, Bhopawar, Gwalior, Indore.</p> <p>Insagarh District, Gwalior.</p> <p>Indore.</p> <p>Isagarh Dist., Gwalior.</p>
MYSORE.	<p>1. <i>Arachis hypogaea</i> Linn. (Leguminosae).</p> <p>Vernacular names: Chinar badam, Bhui muga, Mungphali, Nilakkadalai.</p> <p>2. <i>Chinnamomum Camphor</i> Nees and Eberm (Lauraceae).</p> <p>Vernacular names: Karpur, Kapur, Karppuram.</p> <p>3. <i>Cinnamomum zeylanicum</i> Nees (Lauraceae.)</p>	<p>Chitaldrug, Tumkar, Kolar.</p> <p>Mysore.</p> <p>Badgadi, Perambadi.</p>

1	2	3
MYSORE — <i>contd.</i>	Vernacular names: Dalchini, Ilavangam.	
	4. <i>Citrus aurantium</i> Linn. (Ru- taceae).	Mysore State.
	Vernacular names: Kamla nambu, Narangi, Sangtara, Narangam.	
	5. <i>Citrus medica</i> Linn. Var. <i>Limonum</i> Linn. (Rutaceae).	Mysore State.
	Vernacular names: Bara nebu, Bara nimbu, Gulgul, Madulam.	
	6. <i>Elettaria cardamomum</i> Maton Var. <i>Minuscula</i> Burkill. (Zin- giberaceae).	Kadur District.
	Vernacular names: Elachi, Ila- chi, Chhoti elachi, Ilanji.	
	7. <i>Hydnocarpus wightiana</i> Blu- me. (Bixaceae).	Mysore.
	Vernacular names: Chaulmugra, Kauti, Garudaphala, Mara- vetti.	
	8. <i>Polygala Chinensis</i> Linn. (Polygalaceae).	Mysore.
	Vernacular name: Meradu.	
	9. <i>Santalum album</i> Linn. (San- talaceae).	Mysore, Somnathapur, Shimoga Dist.
	Vernacular names: Chandan, Ingam.	
	10. <i>Acacia catechu</i> Willd (Leguminosae).	Mysore.
	Vernacular names: Kuth, Khaira, Khair, Karungali.	
PEPSU.	1. <i>Papaver Somniferum</i> Linn. (Papaveraceae).	Kapurthala State.
	Vernacular names: Post, Afim, Postaka.	
RAJASTHAN. & AJMER.	1. <i>Acacia senegal</i> Willd. (Le- guminosae).	Ajmer, Aravalli Hills, Dednor Erinpura, Jodhpur, Kishen- garh, between Bhim and Todgarh.
	Vernacular names: Kumta, Sveta, Khadira, Khor.	
	2. <i>Acacia arabica</i> Willd. (Legu- minosae).	Ajmer, Merwara.
	Vernacular names: Babul, Kikar, Karuvel.	
	3. <i>Cassia fistula</i> Linn. (Legu- minosae) (B.P. 1932).	Abu-Sirohi State, Ajmer.
	Vernacular names: Sonali, Amaltas, Aragoram.	
	4. <i>Chenopodium album</i> Linn. (Chenopodiaceae)	Merwara.
	Vernacular names: Bathusag, Chakwit, Parupukkirai.	

1	2	3
RAJASTHAN & AJMER— <i>contd.</i>	<p>5. <i>Citrullus colocynthis</i> Schrad. (Cucurbitaceae)</p> <p>Vernacular names: Makhal, Indrayan, Peykumutti.</p> <p>6. (a) <i>Datura Stramonium</i> Linn (Solanaceae) (b) <i>Datura tatula</i> Linn. (Solanaceae)</p> <p>Vernacular names: Sada dhu- tura, Dhatura Umattaka.</p> <p>7. <i>Papaver Somniferum</i> Linn. (Papaveraceae)</p> <p>Vernacular names: Post, Afim, Postaka.</p> <p>8. <i>Tamarindus indica</i> Linn. (Leguminosae)</p> <p>Vernacular names: Tentul Amil, Imli, Amilam.</p> <p>9. <i>Acacia Catechu</i> Willd. (Leguminosae)</p> <p>Vernacular names: Kuth, Khaira, Khair, Karungali.</p>	<p>Merwara.</p> <p>Beawar, Ajmer, Merwara.</p> <p>Alwar, Bikaner, Hiraoti, Jaipur, Kotah, Merwara, Tonk.</p> <p>Ajmer.</p> <p>Mount Abu.</p>
COORG	<p>1. <i>Elettaria Cardamomum</i> Maton Var. <i>Minuscula</i> Burkill. (Zingiberaceae)</p> <p>Vernacular names: Elachi, Ilachi, Chhoti elachi, Ilanji.</p> <p>2. <i>Ipomoea turpethum</i> R. Br. (Convolvulaceae)</p> <p>Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.</p> <p>3. <i>Lobelia nicotianifolia</i> Heyne. (Campanulaceae).</p> <p>Vernacular names: Nala, Dawal, Kuttuppugaiyilai.</p>	<p>Coorg State.</p> <p>Coorg State.</p> <p>Mercara.</p>
DELHI	<p>1. <i>Acacia arabica</i> Willd. (Legu- minosae)</p> <p>Vernacular names: Babul, Kikar, Karuvel.</p> <p>2. <i>Chenopodium album</i> Linn. (Chenopodiaceae)</p> <p>Vernacular names: Bathusag, Chakwit, Parupukkirai.</p> <p>3. <i>Citrullus Colocynthis</i> Schrad (Cucurbitaceae)</p> <p>Vernacular names: Makhal, Indrayan, Peykumutti.</p> <p>4. <i>Tamarindus indica</i> Linn. (Leguminosae).</p> <p>Vernacular names: Tentul, Amli, Imli, Amilam.</p>	<p>Delhi.</p> <p>Delhi.</p> <p>Delhi.</p> <p>Delhi.</p>

1	2	3
MANIPUR	1. <i>Papaver Somniferum</i> Linn. ( <i>Papaveraceae</i> ). Vernacular names: Post, Afim, Postaka. 2. <i>Valerina Wallichii</i> DC. ( <i>Valerianaceae</i> ). Vernacular names: Mushkbala, Tagara.	Manipur State.  Manipur State.
SAURASHTRA	1. <i>Acacia Senegal</i> Willd. ( <i>Legumi- nosae</i> ) Vernacular names: Kumta Sveta, Khadira, Khor. 2. <i>Arachis hypogaea</i> Linn. ( <i>Leguminosae</i> ) Vernacular names: Chiner badam, Bhui muga, Mung- phali, Nilakkadalai.	Okhla Port (all over)  Bhavnagar, Junagadh, Nawa- nagar, Gondal.
TRAVANCO- RE-COCHIN	1. <i>Acacia arabica</i> Willd ( <i>Legu- minosae</i> ) Vernacular names: Babul, Kikar, Karuvel. 2. <i>Camellia Sinensis</i> Linn. O. Kuntze ( <i>Theaceae</i> ) Vernacular name : Cha. 3. <i>Cinnamomum zeylanicum</i> Nees ( <i>Lauraceae</i> ). Vernacular names: Dalchini, Ilavangam. 4. <i>Citrullus Colocynthis</i> Schrad ( <i>Cucurbitaceae</i> ). Vernacular names: Makhai, Indrayan, Peykumutti 5. <i>Elettaria Cardamomum</i> Maton Var. <i>Minuscula</i> Burkill ( <i>Zingiberaceae</i> ). Vernacular names: Elachi, Ilachi, Chhoti elachi, Ilanji. 6. <i>Eugenia Caryophyllus</i> (Spreng). Sprague. ( <i>Myrtaceae</i> ) Vernacular names: Lavanga, Laung. 7. <i>Hydnocarpus Wightiana</i> Blume ( <i>Bixaceae</i> ). Vernacular names: Chaulmugra, Kauti, Garudaphala, Mara- vetti. 8. <i>Ipomoea turpethum</i> R. Br. ( <i>Convolvulaceae</i> ). Vernacular names: Dhudkalmi, Nishotar, Pitohri, Kumbam.	Trivandrum.  Cardamom Hills.  Kolattu puzha, Quilon.  Trivandrum. Cochin  Government garden Burliar, Koni.  Cochin, Colatoorpolay, Devi- kolam, Kalattupuzha Malay- anthur, Naduvathumuzhi, Quilon.  Variyur.

1	2	3
TRAVAN- CORE COCHIN	9. <i>Lobelia nicotianifolia</i> Heyne (Campanulaceae).	Ponmudi.
—contd.	Vernacular names: Nala, Dawal, Kuttuppugaiyilai.	
	10. <i>Polygala Chinensis</i> Linn. (Polygalaceae).	Muthukuzivayal, Trivandrum.
	Vernacular name : Meradu.	
	11. <i>Ricinus Communis</i> Linn. (Euphorbiaceae)	Quilon.
	Vernacular names: Bherenda, Erendi, Arend, Attagam.	
	12. <i>Santalum album</i> Linn. (Santalaceae)	Achankovil, Quilon, Varkkallai.
	Vernacular names: Chandan, Ingam.	
	13. <i>Strychnos nux-Vomica</i> Linn. (Loganiaceae).	Puliyara.
	Vernacular names: Kuchila, Kara, Kuchla, Karalam.	
	14. <i>Tamarindus indica</i> Linn. (Leguminosae).	Trivandrum
	Vernacular names: Tentul, Amli, Imli, Amilam.	
	15. <i>Acacia catechu</i> Willd. (Leguminosae)	Anjinad, Nanjinad.
	Vernacular names: Kuth, Khaira, Khair, Karungali.	
TRIPURA	1. <i>Cassia fistula</i> Linn. (Legumi- nosae) Vernacular names: Sonali, Amaltas, Aragoram.	Agartala.
	2. <i>Linum. Usitatissimum</i> Linn. (Linaceae) (B.P. 1932)	Agartala.
	Vernacular names : Tisi, Alasi, Alsi, Alshi.	
	3. <i>Ricinus Communis</i> Linn. (Euphorbiaceae).	Agartala.
	Vernacular names: Bherenda, Erendi, Arand, Attagam.	
	4. <i>Tamarindus indica</i> Linn. (Leguminosae).	Agartala.
	Vernacular names: Tentul, Amli, Imli, Amilam.	
	5. <i>Trachyspermum ammi</i> (Linn) Sprague (Umbelliferae)	Agartala.
	Vernacular names: Jowan, Ajwan, Ajwain, Amam.	
BHUTAN	<i>Picraena quassioides</i> Benth. (Simarubaceae)	Bhutan.
	Vernacular names: Bhurungi, Bharangi, Bering.	

1	2	3
SIKKIM	1. <i>Camellia Sinensis</i> Linn. Sikkim. O. Kuntze (Theaceae)	
	Vernacular name: Cha.	
	2. <i>Cinchona Calisaya</i> Weddell Sikkim. (Rubiaceae). (B. P. 1932).	
	3. <i>Cinchona officinalis</i> Linn. Sikkim. (Rubiaceae). (B.P. 1932).	
	4. <i>Cinchona Succirubra</i> Pavon. Rangbi and Poomang plantations (Rubiaceae). (B.P. 1932)	
	5. <i>Ephedra geradiana</i> wall, Sikkim. (including <i>E. nebrodensis</i> Tineo (Gnetaceae)).	
	Vernacular names: Tutgantha, Asmania.	
	6. <i>Linum. Usitatissimum</i> Linn. Sikkim. (Linaceae) (B.P. 1932).	
	Vernacular names: Tisi, Alasi, Alsi, Alshi.	
	7. <i>Pinus Longifolia</i> Linn. Sikkim. (Coniferae).	
	Vernacular names: Saralagach, Chil, Simaidevadari.	
	8. <i>Podophyllum emodi</i> Wall. Chamnaga, Sikkim, Thangu. (Berberidaceae).	
	Vernacular names: Papra, Banwangan, Ban Kakri.	
	9. <i>Rheum emodi</i> Wall. (Poly- gonaceae). Sikkim.	
	Vernacular names: Banglare- vanchi, Ladakirevandachini, Hindi revandchini, Nattir- evalechinni.	

*Names of the Medicinal Plants cultivated all over India*

1. *Coriandrum Sativum* Linn. (Umbelliferae)  
Vernacular names: Dhane, Dhanya, Dhania, Kotamalli.
2. *Dryopteris filix-mas* (Linn.) Schott (Polypodiaceae).  
Found from Bhutan to Kumao and in Khasia. In South India on the western mountains and common in Sikkim.
3. *Foeniculum Vulgare* Mill. (Umbelliferae)  
Vernacular names: Maurai, Panmohuri, Saunf, Sohikirai.
4. (a) *Gelidium cartilagineum* Gaill. } (Gelidisceae)  
(b) *Gelidium carneum* (Huds) Lamouroux }  
Vernacular name: Chinaghash.  
Concentrated on the Indian coasts.
5. *Gossypium* Sp. (Malvaceae).  
Vernacular names: Kapas, Rui, Parutti.
6. *Hordeum distichon* Linn. (Gramineae)
7. *Melaleuca Leucadendron* Linn. (Myrtaceae).  
Vernacular names: Cajuputte, Kayaputi, Kaiyappudai.  
Sometimes planted in Indian gardens. Its cultivation can be expanded in India.
8. *Quercus* sp. (Cupuliferae).  
Quercus species are found both in the eastern and western temperate concentrated on the Himalayas.
9. *Rosmarinus officinalis* Linn. (Labiatae)  
Chiefly in the Botanic gardens as in Ootacamund.
10. *Saccharum officinarum* Linn. (Gramineae).  
Vernacular names: Ganna, Gol, Kalai.
11. *Sesamum indicum* Linn (Pedaliaceae).  
Vernacular names: Till, Ellu.
12. *Thymus Vulgaris* Linn. (Labiatae).  
Botanical gardens as in Ootacamund.
13. *Zea mays* Linn (Gramineae).  
Vernacular names: Bhutta, Makai, Makkasholam.  
This along with Maize, rice, wheat and potatoes are widely cultivated in the country.
14. *Zingiber officinale* Roscoe (Scitamineae)  
Vernacular names: Ada, Adu, Adrak, Sangai.  
Largely cultivated in Madras, Bombay and Bihar States.



## APPENDIX No. 7

### SUMMARY OF THE RECOMMENDATIONS OF THE REPORT OF THE EXPERT COMMITTEE (EXCISE) (Constituted under the Government of India letter No. 33(20)-E.O./49 dated the 5th June, 1950.)

#### *Regarding alcohol and its raw material*

(1) The Committee feels that while it is desirable in the interest of Prohibition, to have control over possession, storage and transport of molasses and mohwra flowers the State Government should be requested to make these articles easily available to trade for genuine industrial purposes.

(2) If the State of Bombay desires to maintain monopoly for the production and supply of alcohol, the rate charged should not be higher than the current market price in other parts of India plus cost of transport.

(3) Regarding restrictions imposed by the Government of Madras on the supply of alcohol to manufacturers, the Committee holds that the upper limit of 300 gallons per year per manufacturer fixed by the Government is arbitrary and detrimental to the industry and should be removed.

(4) Loss of spirit in transit should be considered a trade risk and cannot, therefore, be exempted from payment of duty except in those bonafide cases where the loss is not due to negligence or connivance of the trade, in which cases the exemption may be granted at the discretion of the Excise authorities.

(5) Regarding wastage of spirit in the manufacture of medicinal or toilet preparations, the Committee feels that though no hard or fast rules can be laid down, yet it would be desirable if the Central Revenues Control Laboratory could compare the statistic and draw up a table showing the general variation in the wastage of spirit for the manufacture of each preparation, and lay down a general principle or scales in respect of permissible wastages.

(6) Regarding freight rates, the Committee is of the opinion that the freight rates should not only be the same for all industrial spirit including rectified spirit but also that these rates should be as low as possible.

#### *Manufacture of medicinal preparations*

(1) All manufacture should, as far as possible, be in bond and the concessional rate of duty proposed by the Committee will be applicable to manufacture in bond only. Manufacture outside bond should pay duty at higher rate. Exceptions may be allowed in favour of recognised institutions for reasons enunciated by the Committee in their report.

(2) A list should be compiled by the Centre from the lists available in all the States of the medicines liable to be misused, and should be called "List of restricted medicines and preparations containing spirits" and should be maintained upto date.

(3) Addition to or deletion from this list should be made by the Central Government after reference to the Drugs Controller, India, in consultation with the States and the trade.

(4) Since all spirituous medicinal preparations are proposed to be manufactured in bond and under excise supervision, and since there will be a list of restricted medicines, there should be no control over sale, possession, distribution and inter-State movement of unrestricted types of medicine once duty is paid.

(5) Regarding restricted medicinal preparations it is proposed that their inter-State movement should be regulated by a system of permits.

#### *Denatured Spirits*

(1) The Committee recommends that the Central Government should prescribe, in consultation with the State Governments, the specification of denaturants, and the denaturants so prescribed should not be varied by the State Governments without the approval of the Central Government.

(2) No vend fee or pass fee should be levied on denatured spirit or special denatured spirit.

#### *Homoeopathic Preparations*

(1) Manufacture of Homoeopathic mother tinctures and dilutions should be under bond. Manufacture done outside bond should not be eligible for the concessional rate of duty.

(2) If any State is permitting a particular branch of the industry to manufacture outside bond, the higher rate of duty i.e., Rs. 17-8-0 per proof gallon should be charged. If this is found oppressive relief in other directions may be granted.

(3) There should be no objection to the preparation of mother tinctures and dilutions being conducted in the same premises.

#### *Ayurvedic Preparations*

(1) Genuine Ayurvedic preparations contain generally only self-generated alcohol. Such preparations, except Draksha Asavas and some other Asavas are not potable and, therefore, should not be subjected to any duty. But the manufacture of these preparations containing self-generated alcohol should be under a licence, subject to drawal of samples by Excise Department from the potable and non-potable varieties.

(2) The present distinction in some States of classifying even Ayurvedic preparations with self-generated alcohol as having 10 per cent. or more than 10 per cent. alcohol is unnecessary and should be discontinued.

(3) Manufacture of Draksha Asavas and other Asavas should be under bond. Ayurvedic medical practitioners may be allowed to manufacture outside bond on condition that their preparations will be for the use of their patients and not for sale. Such a practitioner will have to take out a licence, but will not have to pay duty.

(4) Preparations like Mrita Sanjibani Sura or Sudha prepared by distillation or by adding alcohol as an ingredient should be treated as any proprietary medicine of restricted category, and should not be allowed to be manufactured outside the bond.

#### *Toilet Preparations and Essences and Perfumed Spirits*

(1) If rectified spirit is used for the manufacture of these preparations, then such manufacture should be under bond.

(2) As in the case of medicines, a list of toilet preparations and essences containing alcohol which would be restricted should be drawn up in consultation with the Drugs Controller, India.

(3) As restricted toilet preparations are not likely to be abused to the same degree as medicinal preparations, it is not necessary to impose as many restrictions as may be necessary on medicinal preparations of restricted category.

(4) The sale, possession and distribution of toilet preparations, not included in restricted category, should be free from all restrictions once duty is paid.

#### *Excise Supervision*

(1) The cost of Excise supervision should be borne by the industry.

(2) The functions of the Excise staff should be extended to ensuring proper utilisation of spirit in the manufacture of preparation and drawing of samples.

#### *Movements:—(A) Inter-State Movement*

(1) There should be no restriction whatever on the movements of drugs and preparations which are not included in the restricted category.

(2) Products imported should be subjected to the same restrictions as products manufactured in the country.

(3) Regarding restricted goods, the Committee recommends that with a view to relax the existing conditions of passes and permits, these permits should be issued by the manufacturers or the wholesale dealers who are licensed importers/exporters.

(B) *Movement within the State.*—Control should be attempted only over distribution if necessary.

(1) *Licensing.*—The Committee is of the opinion that the whole system of licensing should not only be rationalized, but also should be uniform throughout the country. And to achieve this, the licences should be standardized for all States and their number reduced to the minimum possible.

(2) Licence fees should not be regarded as a source of revenue, they should be regarded only as a step towards effecting the necessary control.

#### *Rates of Duty*

(1) The rate of duty on all spirituous medicinal preparations whether they are of restricted or non-restricted category, should be Rs. 5 per L.P. gallon.

(2) This rate would be applicable only to the preparations manufactured in bond with the exception of a few recognised institutions.

(3) For preparations manufactured outside bond the rate of duty should be higher i.e., Rs. 17-8-0 per L.P. gallon.

(4) Homoeopathic dilutions, if done under bond should pay duty at the rate of Rs. 5.

(5) The rate of duty on toilet preparations or essences containing alcohol and manufactured under bond should be Rs. 5.

(6) For Ayurvedic preparations of the restricted category the rate of duty recommended is Rs. 3 per bulk gallon of the finished product. Other Ayurvedic preparations will be free of duty. For Ayurvedic Suras and Sudhas the rate recommended is Rs. 5 per P.G.

#### *Collection and Allocation of Revenue*

(1) The Committee was of the opinion that while the Centre should frame a uniform set of rules for the collection of revenue, fix the rate of duty, the responsibility for the collection of revenue should remain with the State Governments.

(2) Of the two principles of levy i.e., levy at source and levy at the stage of consumption the Committee recommends the first.

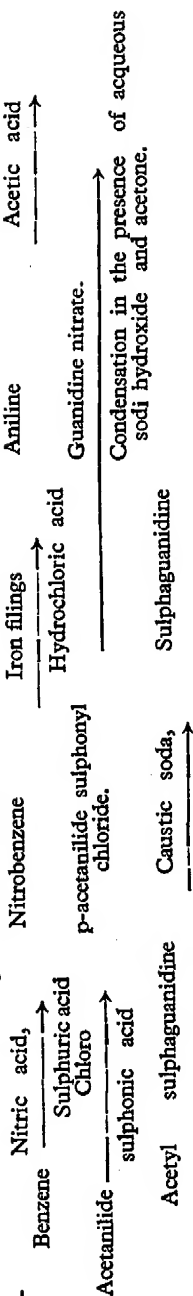
(3) The feasibility of devising another method of levy so as to permit allocation of revenue on the basis of population should be examined.





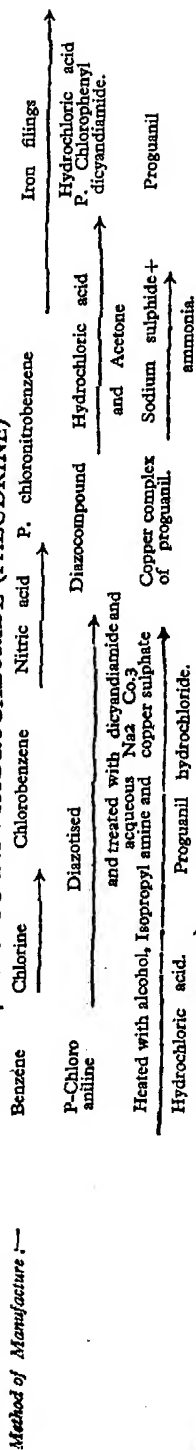
## 3. SULPHAGUANIDINE

Method of manufacture :—



	Benzene	Nitric acid	Sulphuric acid Chloro	Acetanilide	Iron filings	Hydrochloric acid	Acetic acid	Chlorosulphonic acid	Caustic soda	Acetone	Ammonia gas	Calcium cyanamide (20-21 per cent N <sub>2</sub> )	Ammonium	Carbon di-oxide
Nitrobenzene	1.0	0.8	1.1	0.015	...	...	...	...	...	...	0.13	1.6	1.95	0.67
Aniline	1.58	...	...	...	1.9	0.15	...	...	...	...	...	...	...	...
Acetanilide	1.23	...	...	...	...	...	1.3	...	...	...	...	...	...	...
P-Acetanilide Sulphonyl Chloride	1.72	...	...	...	...	...	...	7.87	...	...	...	...	...	...
Acetyl Sulphaguanidine	(1)	...	...	...	...	...	...	...	1.12	1.0	...	...	...	...
Sulphaguanidine	(1.0)	...	...	...	...	3.2	...	...	...	...	0.5	...	...	...
Total Basic Raw Materials Required														
Starting from benzene and calcium cyanamide.														
(a) For 1 lb. of Sulphaguanidine.	1.0	0.8	1.1	0.015	1.9	3.35	1.3	7.87	1.12	1.0	0.63	1.6	1.95	0.67
(b) For 50,000 lbs. of Sulphaguanidine.	50,000	40,000	55,000	750	95,000	1,67,500	65,000	3,93,500	56,000	50,000	31,500	80,000	97,500	33,500
Starting from Acetanilide and Guanidine Nitrate.														
(a) For 1 lb of Sulphaguanidine.	92,000	...	...	...	...	3.2	...	7.87	1.12	1.0	...	...	...	...
Sulphaguanidine.	92,000	...	...	...	...	1,60,000	...	3,93,500	56,000	50,000	...	...	...	...

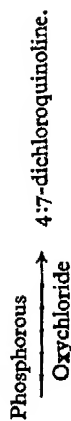
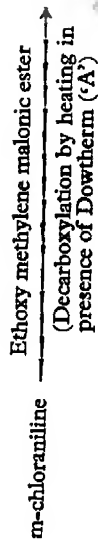
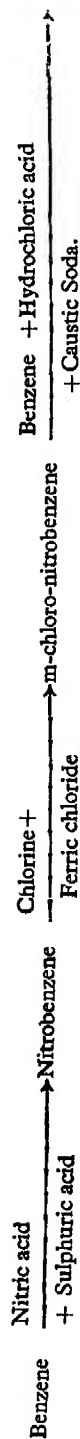
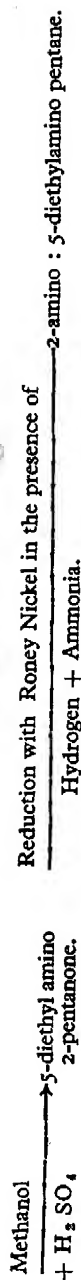
#### 4. PROGUANIL HYDROCHLORIDE (PALUDRINE)



	Benzene <sup>a</sup>	Chlorine	Iron filings	Nitric acid	Sulphuric acid	Hydrochloric acid	Cautic Soda	Benzene <sup>a</sup> (recovered)	Acetone	Rectified Spirit	Isopropyl amine	Copper Sulphate	Sodium Sulphate	Ammonia gas	Soda Ash	Sodium nitrate	Calcium cyanamide	Carbon dioxide
	1.2	1.13	Small Qty.	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
Chlorobenzene (1.41)	...	...	...	0.8	1.2	...	...	...	...	...	...	...	...	...	...	...	2.8	1.28
P-Chloro Nitro benzene (1.25)	...	...	...	...	...	0.25	...	...	...	...	...	...	...	...	...	...	...	...
P-Chloro aniline (1.0)	...	...	2.0	...	...	...	0.11	2.0	...	...	...	...	...	...	...	...	Dicyanamide 0.8	...
Diazo compound (1.0)	...	...	...	...	...	8.0	...	...	0.75	...	...	...	...	...	...	...	...	...
P-Chloro phenyl dicyandiamide	...	...	...	...	...	...	...	...	...	1.0	0.9	1.12	...	...	...	...	...	...
Copper Complex of proguanil.	...	...	...	...	...	...	...	...	...	...	...	...	0.72	0.16	2.24	0.6	...	...
Proguanil Hydrochloride.	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...
<b>Total Raw Materials Required.</b>																		
Starting from Benzene and Calcium cyanamide.																		
(a) for 1 lb. of Paludrine.	3.2	1.13	2.0	0.8	1.2	8.25	0.11	...	0.75	1.0	0.9	1.12	0.72	0.16	2.24	0.6	2.8	1.28
(b) for 30,000 lbs. of Paludrine.	96,000	33,900	60,000	24,000	36,000	2,47,500	3,300	...	22,500	30,000	27,000	33,600	21,600	4,800	67,200	18,000	84,000	38,400
Starting from P-chloroaniline and dicyandiamide.																		
(a) for 1 lb. of Paludrine.	...	...	...	8.0	...	...	...	...	0.75	1.0	0.9	1.12	0.72	0.16	2.24	0.6	Dicyanamide 0.8	...
(b) for 30,000 lbs. of Paludrine.	...	...	...	2,40,000	...	...	...	...	22,500	30,000	27,000	33,600	21,600	4,800	67,200	18,000	24,000	...



## 5. CHLOROQUINE, DIPHOSPHATE

*Method of Manufacture :**Stage No. 1**Stage No. 2**Stage No. 3*

(A) Synthesis of 4:7-Dichloroquinoline

	Benzene*	Nitric acid	Sulphuric acid	Soda Ash	Chlorine	Ferric chloride	Iron filings	Hydrochloric acid (1.16)	Caustic Soda	*Benzene (recovered later)	Ethoxymethylene melonic ester	Petroleum Naptha.	Dowtherm A.	Bithanol (solvent)	Phosphorous oxychloride
Nitrobenzene	0.96	0.72	1.0	0.015	...	...	...	...	...	...	...	...	...	...	...
M-chloronitro benzene	(1.6)	...	...	...	1.2	0.03	...	...	...	...	...	...	...	...	...
m-chlor-aniline]	(1.25)	...	...	...	...	...	2.0	0.25	0.11	2.00	...	...	...	...	...
4-hydroxy-7 chloroquinoline	(1.0)	...	1.5	...	...	...	...	...	2.12	...	1.5	0.05 (gallons)	0.5	0.4 (gallons)	...
4:7 dichloroquinoline	( )	...	...	...	...	...	...	...	...	...	...	...	...	...	1.0

	Diethylamino ethanol.	Thionyl chloride.	Dry* Benzene	Sodium aceto-acetic ester	Methanol (recovered)	Hydrogen	Ammonia	Roney Nickel
Diethylamino ethyl chloride	1.0	1.5	0.5	...	...	...	...	...
Ethyl-diethyl aminoethyl-aceto acetate	( )	...	...	1.3	...	...	...	...
5-diethyl amino 2-pentanone	( )	...	...	...	0.1 (gallons)	...	...	...
2-amino-5-diethylamino pentane (Novol diamine)	( )	...	...	...	...	0.08	0.5	0.01

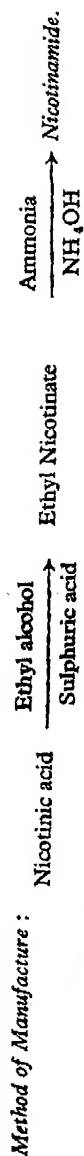
(B) Synthesis of 2-Amino-5 Diethylamino n-pentane (Novol Diamine)

## (C) Interaction of 4 : 7-Dichloroquinoline and 2-Amino-5-Diethyl Amino Pentane.

Chloroquin di-phosphate.	4 : 7-dichloro quinoline.		2-amino-5-diethyl amino pentane.		Phenol.	Phosphoric acid.
	.	.	.	.		
	.	.	.	.	0.15	0.5
	.	.	(1.0)			
<i>Total Basic Raw Materials required.</i>						
Starting from Benzene and diethylamino ethanol.						
	For 1 lb. of chloroquin.	For 30,000 lbs. of chloroquin.	Starting from m-chloroaniline and diethylamino ethanol.			
			For 1 lb. of chloroquin.	For 30,000 lbs. of chloroquin.		
Benzene.	3.46	1,03,800	m-chloroaniline	1.0	30,000	
Nitric acid	.	21,600		.	.	45,000
Sulphuric acid	2.5	75,000		1.5	.	.
Soda Ash	0.015	450		.	.	.
Chlorine.	1.2	36,000		.	.	.
Ferric chloride.	0.03	900		.	.	.
Iron filings	2.0	60,000		.	.	.
Hydrochloric acid	0.25	7,500		2.12	63,600	
Caustic soda	2.13	63,900		1.5	45,000	
Ethoxy methylene	1.5	45,000				
Melonic ester.	.					
Petroleum Naptha	0.05 (gallons)	1,500 (gallons)		0.05 (gallons)	1,500 (gallons)	
Dowtherm A.	0.5	15,000		0.5	1,500	
Ethanol	0.4 (gallons)	12,000 (gallons)		0.4 (gallons)	1,200 (gallons)	
Phosphorous oxychloride	1.0	30,000		1.0	30,000	
Diethylamine ethanol	1.0	30,000		1.0	30,000	
Thionyl chloride	1.5	45,000		1.5	45,000	
Sodium aceto-acetic ester	1.3	39,000		1.3	39,000	
Hydrogen	0.08	2,400		0.08	2,400	
Ammonia	0.5	15,000		0.5	1,500	
Roney Nickel.	0.01	300		0.01	300	
Phenol	0.15	4,500		0.15	4,500	
Phosphoric acid	0.5	15,000		0.5	15,000	



## 6(b). NICOTINAMIDE

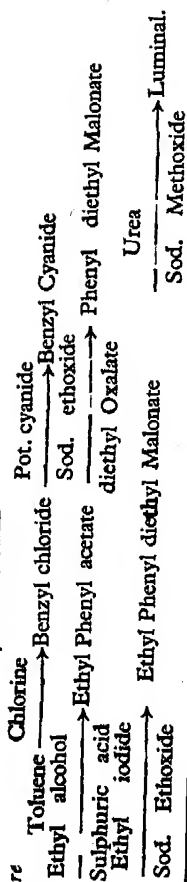


	Nicotinic acid	Sulphuric acid (66° Be)	Soda Ash	Ethyl alcohol absolute	Ether	Ice	Ethyl acetate	Dry ammonia	Liquor NH <sub>4</sub> OH (0.9 Sp.Gr)	Charcoal	Calcium chloride
	1.50	2.86	2.50	14.10	1.8	8.0	..	..	..	..	..
ethyl Nicotinate	1.35	..	..	..	0.05	5.0	3.0	0.25	3.9	0.06	0.2
Nicotinamide	(1.0)										
Starting from Nicotinic acid											
(a) For 1 lb. of Nicotinamide	1.50	2.86	2.5	14.10	1.85	13.0	3.0	0.25	3.9	0.06	0.2
(b) For 200 lbs. of Nicotinamide.	300	572	500	2,820	370	2,600	600	50	780	12	4.0

Basic Raw materials required

## 7. LUMINAL

## Method of manufacture



	Toluene	Chlorine	Pot. cyanide	Diethyl-oxalate	Ethyl alcohol (abs)	Sulphuric acid	Ethyl iodide	Urea	Sodium (metal)	Methyl alcohol	Mag. sulphate	Ether
	4.3	3.3	...	...	...	...	...	...	...	...	...	...
Benzyl chloride	(4.3)	...	2.12	...	...	...	...	...	...	...	...	...
Benzyl cyanide	(3.42)	...	...	...	23.0	7.7	...	...	...	...	...	...
Ethyl Phenyl acetate	( )	...	...	3.75	...	...	2.0	1.1	1.2	3.1	0.5	1.5 litres
Luminal	(1.0)	...	...	...	...	...	...	...	...	...	...	...
Total Basic Raw Materials Required												
Starting from Toluene.												
(a) For 1 lb. of luminal.	4.3	3.3	2.12	3.75	23.0	7.7	2.0	1.1	1.2	3.1	0.5	1.5 litres.
(b) For 5000 lbs. of luminal.	21,500	16,500	10,600	18,750	1,15,000	38,500	10,000	5,500	6,000	15,500	2,500	7,500 litres.
Starting from Ethyl Phenyl acetate and diethyl oxalate.												
(a) For 1 lb. of luminal.				diethyl oxalate. 3.75			2.0	1.1	1.2	3.1	0.5	1.5 litres.
(b) For 5000 lbs. of luminal.				18,750			10,000	5,500	6,000	15,500	2,500	7,500 litres.

## 8. CHLORAL HYDRATE

*Method of manufacture :*

Ethyl alcohol	Chlorine + Sulphuric acid	Chloral hydrate
	Ethyl alcohol 0.65 ↓ (1.0)	Chlorine 2.10 Sulphuric acid 1.6
Chloral hydrate		

*Total basic raw materials required*

(a) For 1 lb. of chloral hydrate.

Ethyl alcohol	Chlorine	Sulphuric acid
0.65	2.10	1.6

(b) For 35,000 lbs. of Chloral hydrate.

22,750	73,500	56,000
--------	--------	--------

## 9. ETHER

*Method of manufacture :*

Ethyl alcohol	Sulphuric acid	Ether	Purified by washing with caustic soda soln. and fractionated	Ether Pure
	Rectified spirit (92 %)		Caustic soda	Sulphuric acid (100 %)
	1.42 (1.0)		0.014	0.0012
Ether				

*Total basic raw materials required*

(a) For 1 lb. of Ether (Anaesthetic and B.P.)

1.42	0.014	0.0012
------	-------	--------

(b) For 3,40,000 lbs. of Ether (Anaesthetic and B.P.)

4,82,800	4,760	408
----------	-------	-----

## 10. CHLOROFORM

*Method of manufacture:* Ethyl alcohol. Bleaching Powder Chloroform.*First Method.*

Rectified spirit (94 %) Bleaching powder (33 %)

0.75 10.0

↓

Chloroforme (1.0)

*Second Method.*

Acetone Bleaching powder

0.57 6.0

↓

Chloroform (1.0)

*Total basic raw materials required**Starting from rectified spirit.*

(a) For 1 lb. of chloroform.

Rectified spirit	Bleaching powder
0.75	10.0

(b) For 1,00,000 lbs. of Chloroform.

75,000	10,00,000
--------	-----------

*Starting from Acetone.*

(a) For 1 lb. of Chloroform

Acetone.	Bleaching powder
0.57	6.0

(b) For 1,00,000 lbs. of Chloroform.

57,000	6,00,000
--------	----------

## 11. ETHYL CHLORIDE

*Method of manufacture:*

Ethyl alcohol	Hydrochloric acid	—Ethyl chloride.
	+ Calcium chloride.	

Ethyl alcohol (94 %)	Hydrochloric acid (1.16)	Calcium chloride
----------------------	--------------------------	------------------

Ethyl chloride	1.05 1.0 ↓	2.85	0.9
----------------	---------------	------	-----

*Total basic raw materials required*

(a) For 1 lb of Ethyl chloride.	1.05	2.85	0.9
(b) For 50,000 lbs of Ethyl chloride.	52,500	1,42,500	45,000



सत्यमेव जयते





	Benzene	Sulphuric acid	Caustic* soda	Arsenious oxide	Nitric acid (1.4)	Mag. chloride	Soda ash	Rectified spirit (recovered)	Sodium hydro-sulphite	Formalin	Caustic* soda
Arspnenamine or Sal- varsan.	(-)	..	..	..	..	..	0.5	40.0	..	Sodium Formaldehyde Sulphoxylate (1.25)	
Neorsphenamine	1.0										
<i>Total basic Raw Materials required</i>											
<i>Starting from Benzene and Formalin.</i>											
(a) For 1 lb. of Neorsphenamine.	4.1	15.23	7.18	3.5	5.4	4.6	0.5	40.0	26.44	1.1	
(b) For 1000 lbs. of Neorsphenamine.	4,100	15,230	7,180	3,500	5,400	4,600	500	40,000	26,440	1,100	
<i>Starting from 3-Nitro-4-hydroxy phenyl arsinic acid and Sodium Formaldehyde Sulphoxylate.</i>											
(a) For 1 lb. of Neorsphenamine.											
3-Nitro-4-hydroxy phenyl arsinic acid				Mag. Chloride		Soda Ash	Rectified Spirit		Sodium hydro-Sulphite	Sodium Formaldehyde Sulphoxylate	
(b) For 1000 lbs. of Neorsphenamine.	(-)			4.6		0.5	40.0		24.6	1.25	
(-)				4,600		400	40,000		24,600	1,250	



Benzene	Nitric acid	Sulphuric acid	Soda ash	Iron borings	Hydrochloric acid	Arsenious oxide	Oxalic acid	Caustic potash	Magnesium chloride	Rectified spirit (recovered)	Sodium hydro-sulphite	Formalin	Caustic soda
---------	-------------	----------------	----------	--------------	-------------------	-----------------	-------------	----------------	--------------------	------------------------------	-----------------------	----------	--------------

*Total Basic Raw Materials Required.*

*Starting from Benzene and Formalin.*  
(1) for 1 lb. of Nearsphenamine.

4.58 10.1 15.1 0.068 8.72 0.67 4.1 4.7 1.0 4.6 40.0 25.84 1.1 0.43  
(2) for 1,000 lbs. of Nearsphenamine.

*Starting from aniline and Sodium Formaldehyde Sulphoxylate*  
(1) for 1 lb. of Nearsphenamine.

4.58 10.1 15.1 0.068 8.72 0.67 4.1 4.7 1.0 4.6 40.0 25.84 1.1 0.43  
Aniline 6.1 6.5 10.1 0.5 .. .. 4.1 4.7 1.0 4.6 40.0 24.0 .. 1.25  
(2) for 1,000 lbs. of Nearsphenamine.

6.100 6.500 10.100 500 .. .. 4.100 4.700 1.000 4.600 40,000 24,000 .. 1,250

*Starting from 4-hydroxy-3-Nitro phenyl Arsenic acid and Sodium Formaldehyde Sulphoxylate.*  
(1) for 1 lb of Nearsphenamine

4-Hydroxy-3-nitro phenyl arsenic acid. (—)  
Magnesium chloride. 4.6  
Sodium Formaldehyde Sulphoxylate. 1.25  
Sodium Hydro Sulphite. 24.0  
Sodium Carbonate. 0.5  
Rectified Spirit. 40.0



## Second method (from aniline)

Benzene	Nitric acid	Sulphuric acid	Soda ash	Iron borings	Hydrochloric acid	Arsenious oxide	Oxalic acid	Sodium bisulphite	Caustic potash	Mag. chloride	Sodium hydro-sulphite	Formalin	Rectified spirit.
2.92	2.3	3.16	0.044	5.57	0.43	..	..	..	..	..	..	..	..
<b>Aniline†</b>													
	..	..	..	..	..	2.64	..	..	..	..	..	..	..
<b>P-arsenic acid.</b>													
	..	..	..	..	..	..	3.04	..	..	..	..	..	..
<b>Oxanilarsani-lic acid</b>													
	4.16	7.2	..	..	..	..	..	..	..	..	..	..	..
<b>Mono nitro arsenic acid.</b>													
	..	..	..	..	..	..	..	..	0.64	..	..	..	..
<b>4-hydroxy-3-Nitro Phenyl arsenic acid.</b>													
	..	..	..	..	..	..	..	..	..	3.68	15.4	..	..
<b>Arsphenamine.</b>													
	..	..	..	..	..	..	..	0.65	..	..	..	0.3	20.0
<b>Sulphars phenamine.</b>													
	..	..	..	..	..	..	..	..	..	..	..	..	..

Total Basic Raw Materials Required.

## Starting from Benzene.

(a) for 1 lb. of Sulpharsphenamine.

Benzene.

2.92 6.46 10.36 0.044 5.57

(b) for 1,500 lbs. of Sulpharsphenamine.

4380 9,590 15,540 66 8,555

Starting from 4-hydroxy-3-Nitro phenylarsinic acid.

(a) for 1 lb. of Sulpharsphenamine.

4-hydroxy-3-Nitro phenyl arsenic acid

Sodium bisulphite

Caustic potash

Mag. Chloride

Sodium hydro-sulphite

Formalin

Rectified Spirit

.. 0.64 0.65 2.64 3.04 0.65 0.64 3.68 15.4 0.3 20.0

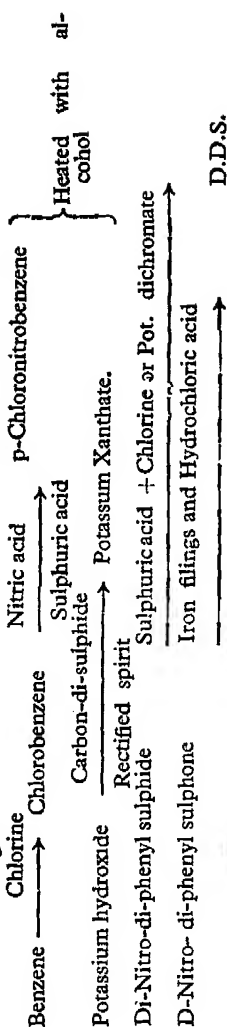
(b) for 1,500 lbs. of Sulpharsphenamine.

.. 960 975 3,960 4,560 975 960 5,520 23,100 450 30,000

†Aniline recovered, 1.1 lb.

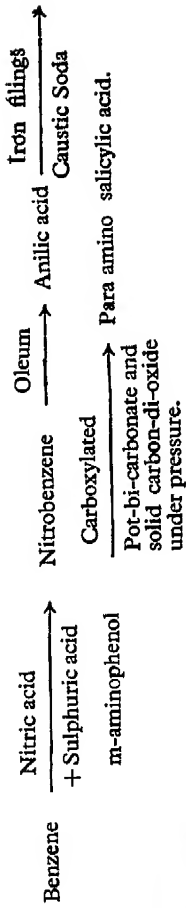
## 14. DI-AMIDO-DI-PHENYL-SULPHONE (D.D.S.)

Method of Manufacture :



	Chlorine	Iron filings	Nitric acid	Sulphuric acid	Acetic acid	Soda Ash	Hydrochloric acid	Pot. hy-dro-xide	Recti-fied spirit	Carbon-di-sul-phide
Chlorobenzene	1.5	1.4	..	..	..	..	..	1.0	19.6	1.52
p-Chloronitrobenzene	1.77	..	1.0	1.5	..	..	..	..	..	..
Di-nitro-di-phenyl sulphid	( )	..	..	0.1	0.64 or 2.00	0.6	0.56	..	..	..
Di-nitro-di-phenyl sulphone	( )	..	..	..	..	..	0.45	..	..	..
Di-amido-di-phenyl sulphone	1.0	4.5	..	..	..	..	..	..	..	..
<i>Total Basic Raw Materials Required.</i>										
Starting from benzene.										
(a) for 1 lb. of D. D. S.	1.5	1.4	4.5	1.0	1.6	0.64 or 2.00	0.56	1.0	19.6	1.52
(b) for 16,000 lbs. of D.D.S.	24,000	22,400	72,000	16,000	25,600	10,240 or 32,000	8,960	16,000	313,600	24,320
Starting from p-chloronitrobenzene.										
(a) for 1 lb. of D. D. S.	1.57	..	4.5	..	0.1	0.64 or 2.00	0.56	1.0	19.6	1.52
(b) for 16,000 lbs. of D. D. S.	25,120	..	72,000	..	1,600	10,240 or 32,000	8,960	16,000	313,600	24,320

## 15. P. A. S. (PARA-AMINO SALICYLIC ACID)

*Method of Manufacture :*

	Benzene	Nitric acid	Sulphuric acid	Soda Ash	Oleum 25% of SO <sub>3</sub>	Common salt	Iron filings	Caustic soda	Pot. bi-carbonate	Carbon-di-oxide (solid)
Nitrobenzene	0.72	0.56	0.78	0.011	..	..	..	..	..	..
Anilic acid	(1.2)	..	..	..	3.72	2.03	..	..	..	..
m-aminophenol	(2.0)	..	..	..	..	..	2.4	4.5	..	..
Carboxylated.	(0.8)	..	..	..	..	..	..	..	4.4	1.47
P. A. S.	(1.0)	..	..	..	..	..	..	..	..	..

Total Basic Raw Materials Required.

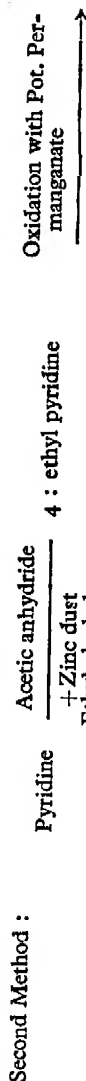
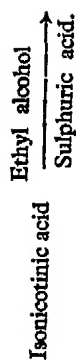
*Starting from benzene.*

(a) For 1 lb. of P. A. S.	0.72	0.56	0.78	0.011	3.72	2.03	2.4	4.5	4.4	1.47
(b) For 1,05,000 lbs. of P. A. S.	75,600	58,800	81,900	1,155	3,90,600	2,13,150	2,52,000	4,72,500	4,62,000	1,54,350
Starting from m-aminophenol.										
(a) For 1 lb. of P. A. S.	m-aminophenol	Pot. bicarbonate.	Carbon-di-oxide.							
	0.8	4.4	1.47							
(b) For 1,05,000 lbs. of P. A. S.	84,000	4,62,000	1,54,350							



## 16. ISONICOTINIC ACID HYDRAZIDE (INH)

## METHOD OF MANUFACTURE : First Method :



## FIRST METHOD :

	Gamma-picoline permanganate	Pot-ethyl picolate	Ethyl Sulphuric acid	Soda Ash	Ether	Urea	Caustic soda	Chlorine	Gelatine	Sulphuric acid	Caustic potash
Isonicotinic acid	1.10	3.72	..	..	..	1.74	3.09	2.118	0.27	7.92	..
			(1.24)	..	11.6	2.3	2.2	1.6		Hydrazine Sulphate (1.95)	1.5
Ethyl Isonicotinate	..	..	..	..	..	..	..	..		Hydrazine Hydrate (0.6)	..
Isonicotinic acid hydrazide	..	..	..	..	..	..	..	..			..

Starting from Gamma-picoline and Urea.

(a) For 1 lb. of INH.

Qd For 20,900 lbs. of INH

## Total Basic Raw Materials Required

1.10	3.72	11.6	10.22*	2.2	1.6	1.74	3.09	2.118	0.27	..	1.5
2.299	77.748	2.42,440	2,13,598	45,980	33,440	36,366	64,581	4,42,666	5,643	..	31,350

Starting from Gamma-picoline and Hydrazine Hydrate.  
(a) For 1 lb. of INH.

	Pot. Per- manganate	Ethyl alcohol	Sulphuric acid	Soda Ash	Ether	Hydrazine Hydrate
1.10	3.72	11.6	2.3	2.2	1.6	0.6

(b) For 20,900 lbs. of INH.

2,299	77,748	2,42,440	48,070	45,980	33,440	12,540
-------	--------	----------	--------	--------	--------	--------

## SECOND METHOD

Pyridine	Acetic anhydride	Acetic acid	Zinc dust	Pot. permanganate	Ethyl alcohol	Sulphuric* acid	Soda Ash	Ether	Urea	Caustic Soda	Chlorine	Gelatine	Sulphuric acid*	Caustic Potash
2.7	15.0	2.7	6.1	7.3	..	..	..	..	1.74	3.09	2.118	0.27	7.92	..
↓											↓			
Isonicotinic acid (1.24)	..	..	..	..	11.6	2.3	2.2	1.6	Hydrazine Sulphate (1.95)	..	↓	Hydrazine Hydrate.	1.5	
↓														
Ethyl Isonicotinate (1.25)	..	..	..	..	..	..	..	..	..	..	Hydrazine Hydrate.	0.6		
↓														
Isonicotinic acid Hydrazide (1.0)	..	..	..	..	..	..	..	..	..	..				

Starting from Pyridine and Urea.

(a) For 1 lb. of INH.

2.7	15.0	2.7	6.1	7.3	11.6	10.22*	2.2	1.6	1.74	3.09	2.118	0.27	..	1.5*
-----	------	-----	-----	-----	------	--------	-----	-----	------	------	-------	------	----	------

(b) For 20,900 lbs. of INH.

56,430	3,13,500	56,430	1,27,490	1,52,570	2,42,440	2,13,598	45,980	33,440	36,366	64,581	4,42,666	5,643	..	31,350
--------	----------	--------	----------	----------	----------	----------	--------	--------	--------	--------	----------	-------	----	--------

Starting from pyridine and hydrazine hydrate.

(a) For 1 lb. of INH.

2.7	15.0	2.7	6.1	7.3	11.6	2.3	2.2	1.6	Hydrazine hydrate 0.60					
-----	------	-----	-----	-----	------	-----	-----	-----	---------------------------	--	--	--	--	--

(b) For 20,900 lbs. of INH.

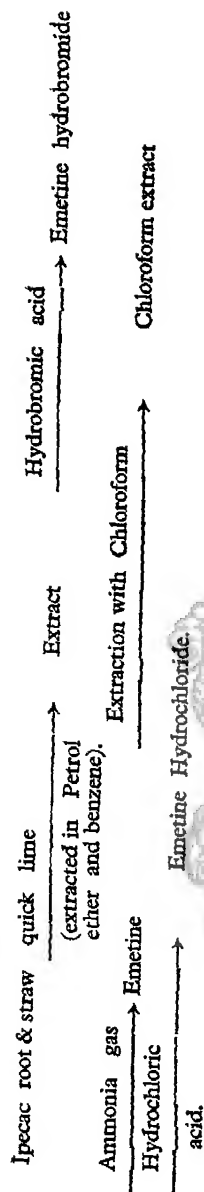
56,430	3,13,500	56,430	1,27,490	1,52,570	2,42,440	48,970	45,980	33,440	12,540					
--------	----------	--------	----------	----------	----------	--------	--------	--------	--------	--	--	--	--	--

Total Basic Raw Materials Required.



# 18. EMETINE HYDROCHLORIDE

*Method of manufacture:*



Ipecac root  
50.0  
↓  
Emetine Hydrochloride (1.0)

Straw  
12.5

Emetine Hydrochloride.

Quick lime

12.5

Hydrobromic acid

2.5

Ammonia

0.5

Hydrochloric acid

1.0

*Total Basic Raw Materials Required*

(a) for 1 lb. of Emetine Hydrochloride.

50

12.5

12.5

2.5

0.5

1.0

(b) for 275 lbs. of Emetine hydrochloride

13,750

3,438

3,438

688

138

275

# 19. CODEINE

Method of manufacture:

Morphine

Treated with Phenyl Trimethyl Ammonium benzene in alcoholic solution under pressure

Morphine

Rectified spirit

Methyl benzene sulphonate

Di-methylaniline

..

0.738

0.53

1.14

↓

Codeine

1.0

Phenyl trimethyl ammonium benzene sulphonate

Total Basic Raw Materials Required

(a) For 1 lb. of Codeine.

(b) For 363 lbs. of Codeine:

1.14

..

0.738

0.53

414

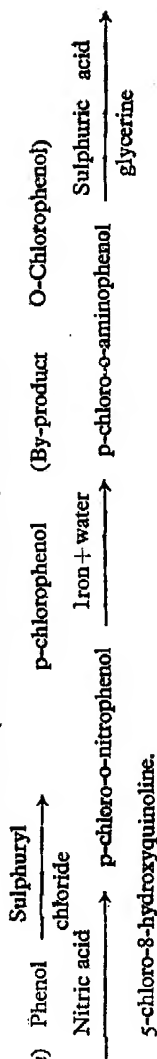
..

268

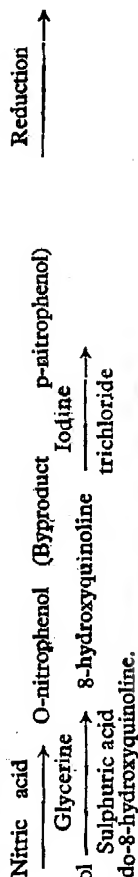
192

## VIOFORM (IDO-CHLOROXYQUINOLINE)

**Method of manufacture:**  
**(First Method Preferred)**



(Second method): (b) Phenol

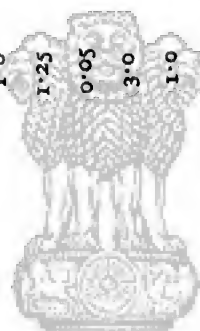


(a) **FIRST METHOD:**

[illegible]

*Total Basic Raw Materials Required*  
*Starting from Benzene*      *Starting from Phenol*      *Starting from 5-chloro-8-hydroxyquinoline.*

	For 1 lb. of Vioform	For 15,000 lbs. of Vioform	Phenol.	For 1 lb. of Vioform	For 15,000 lbs. of Vioform	5-chloro-8-Hydroxyquinoline.	For 1 lb. of Vioform	For 15,000 lbs. of Vioform
Benzene . . . . .	1.0	15,000		1.13	16,960		0.66	9,900
Sulphuric acid . . . . .	3.0	45,000		..	..		..	..
Caustic soda . . . . .	1.7	25,500		..	..		..	..
Sulphuryl chloride . . . . .	1.8	27,000		1.8	27,000		..	..
Nitric acid . . . . .	1.0	15,000		1.0	15,000		..	..
Iron powder . . . . .	1.25	18,750		1.25	18,750		..	..
Hydrochloric acid . . . . .	0.05	750		0.05	750		..	..
Glycerine . . . . .	3.0	45,000		3.0	45,000		..	..
Iodine . . . . .	1.0	15,000		1.0	15,000		1.0	15,000
Pot. Iodide . . . . .	2.0	30,000		2.0	30,000		2.0	30,000
Ammonia . . . . .	..	..		..	..		..	..
<i>(b) SECOND METHOD</i>								
Benzene	2.13	3.0	3.56	..	..	..	..	..
Sulphuric acid	..	..	..	..	..	..	..	..
Caustic soda	..	..	..	..	..	..	..	..
Sodium nitrate	..	..	..	..	..	..	..	..
Sodium sulphide	..	..	..	..	..	..	..	..
Glycerol	..	..	..	..	..	..	..	..
Rectified spirit	..	..	..	..	..	..	..	..
Iodine	..	..	..	..	..	..	..	..
Chlorine	..	..	..	..	..	..	..	..
Sodium carbonate	..	..	..	..	..	..	..	..



Phenol . . . . .	2.37	7.65	..	3.8	1.45	1.4	2.2	..	1.5
8-Hydroxyquinoline . . . . .	0.5	..	..	..	..	..	..	0.45	..
Vioform . . . . .	(1.0)	..	..	..	..	..	..	..	..







६ मन्मथेव जयन्ते

Total Basic Raw Materials Required

*Starting from benzene.*

(a) For 1 lb. of Carbarzone .

(b) For 700 lbs. of Carbarzone

**Starting from aniline.**

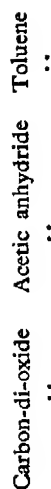
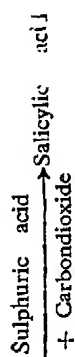
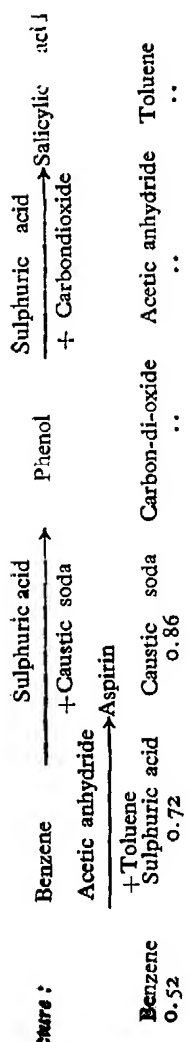
## Aniline

(a) For 1 lb. of Carbarsone .

(b) For 700 lbs. of Carbarbone

## 24. ASPIRIN

## Method of Manufacture :



Phenol	↓	(0.57)	0.32	0.25	0.39	..	..
Salicylic acid	↓	(0.80)	..	..	..	1.0	0.64
Aspirin	↓	(1.0)	..	..	..	..	..

Total Basic Raw Materials Required.

## Starting from Benzene

(a) For 1 lb. of Aspirin	0.52	1.04	1.11	0.39	1.0	0.64
(b) For 15,00,000 lbs. of Aspirin	7,80,000	15,60,000	16,65,000	5,85,000	15,00,000	9,60,000

## Starting from Salicylic acid

	Salicylic acid	Acetic anhydride.	Toluene.
(a) For 1 lb. of Aspirin	0.8	1.0	0.64
(b) For 15,00,000 lbs. of Aspirin.	12,00,000	15,00,000	9,60,000

# 25. SODIUM SALICYLATE

Method of Manufacture :		Sulphuric acid +Caustic soda		Phenol	Sulphuric acid +Carbon-di-oxide		Salicylic acid
	Benzene	Sodium Carbonate			Carbon dioxide		Sodium Carbonate
	0.54	0.74		Sodium Salicylate. Caustic soda	..		..
	↓	0.9		0.9	..		..
Phenol.	(0.6)	0.34		0.26	0.41		0.38
Salicylic acid	(0.86)	—		—	—		—
Sodium Salicylate	(1.0)	—		—	—		—

Phenol.  
Salicylic acid  
Sodium Salicylate



## Starting from Benzene

(a) For 1 lb. of Sodium Salicylate.	0.54	1.08	1.16	0.41	0.38
(b) For 4,50,000 lbs. of sodium Salicylate.	2,43,000	4,86,000	5,22,000	1,84,500	1,71,000

## 26. CHLOROBUTANOL OR CHLORESTONE

Method of Manufacture	Treated with				
	Ethyl alcohol				
	Bleaching powder				
	Acetone + Caustic				
	potash + alcohol (absolute)				
	→ Chloroform				
	→ Chlorobutanol.				
	Bleaching powder (33%)	Rectified spirit	Acetone	Caustic potash	Alcohol (absolute)
	10.0	0.75	..	..	..
	↓				
Chloroform . . . . .	(1.0)		6.0	0.375	1.5
	↓				
Chloro-butanol . . . . .	(1.0)				

## Total Basic Raw Materials Required.

## Starting from bleaching powder .

(a) For 1 lb. of chlorobutanol	10.0	0.75	6.0	0.375	1.5
(b) For 250 lbs. of chlorobutanol.	2,500	187.5	1,500	93.75	225

## Starting from Chloroform

	Chloroform				
(a) For 1 lb. of chlorobutanol	1.0		6.0	0.375	1.5
(b) For 250 lbs. of chlorobutanol.	250		1,500	93.75	225

## 27. CINCHOPHEN (ATOPHEN)

<i>Method of Manufacture</i>	Commer- cial Indigo	Nitric acid	Acetophenone + Caus- tic potash + Rectified spirit			
		Chromic acid	Isatin			
	Cinchophen.					
	Indigo	Nitric acid	Chromic acid	Acetophe- -none	Caustic Potash	Rectified spirit
	0.93	1.40	0.55	..	..	..
Isatin . . . . .	0.735	..	..	0.60	0.12	7.5
Cinchophen . . . . .	1.0					

## Total Basic Raw Materials Required.

## Starting from Indigo

(a) For 1 lb. of cinchophen	0.93	1.4	0.55	0.6	0.12	7.5
(b) For 2,500 lbs. of cinchophen	2,325	3,500	1,375	1,500	300	18,750

## Starting from Isatin and Acetophenone.

	Isatin					
(a) For 1 lb. of cinchophen.	0.735	..	..	0.6	0.12	7.5
(b) For 2,500 lbs. of cinchophen.	1837.5	..	..	1,500	300	18,750

## 28. ARGENTI PROTEINUS

*Method of Manufacture :* Silver Nitrate  $\xrightarrow{\text{Ammonia}}$  Silver oxide  $\xrightarrow{\text{Suspended in Casein}}$  solution and heated and evaporated in vacuum

Argenti Proteinus.

	Silver Nitrate	Casein	Ammonia Liquor
	0.13	0.9	0.8
Protenate . . . . . (strong type)	1.0		

*Total Raw Materials Required.*

(a) For 1 lb. of Argenti Proteinus.	0.13	0.9	0.8
(b) For 1,500 lbs. Argenti Proteinus.	195	1,350	1,200

## 29. SACCHARIN

*Method of Manufacture:* Toluene  $\xrightarrow{\text{Treated with chloro-sulphonic acid (Below } 0^{\circ}\text{C.)}}$  Toluene sulphonyl chloride (mixed)  $\xrightarrow{\text{filtered}}$  O. Toluene sulphonyl chloride  $\xrightarrow{\text{Ammonia}}$  O. Toluene sulphonamide

Purified by fractional precipitation to  $\rightarrow$  Saccharin.

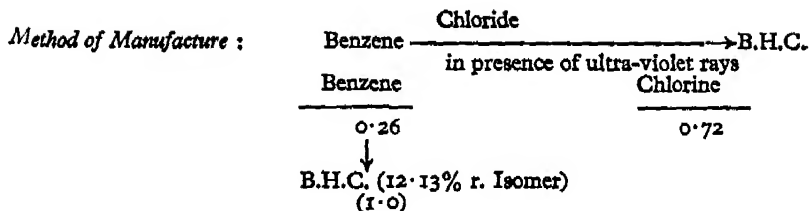
Hydrochloric acid and Oxidised with Pot. Permanganate Solution.

	Toluene	Chlorosulphonic acid	Ammonia	Pot. Permanganate
	1.9	7.5	..	..
	↓			
O-Toluene sulphonyl chloride . . . . .	(2.2)	..	0.5	..
	↓			
O-Toluene sulphonamide . . . . .	(9.43)	..	..	2.5
	↓			
Saccharin . . . . .	(1.0)			

*Total Raw Materials Required.*

(a) For 1 lb. of Saccharin . . . . .	1.9	7.5	0.5	2.5
(b) For 2,00,000 lbs. of Saccharin	3,80,000	15,00,000	1,00,000	5,00,000

## 30. B.H.C.

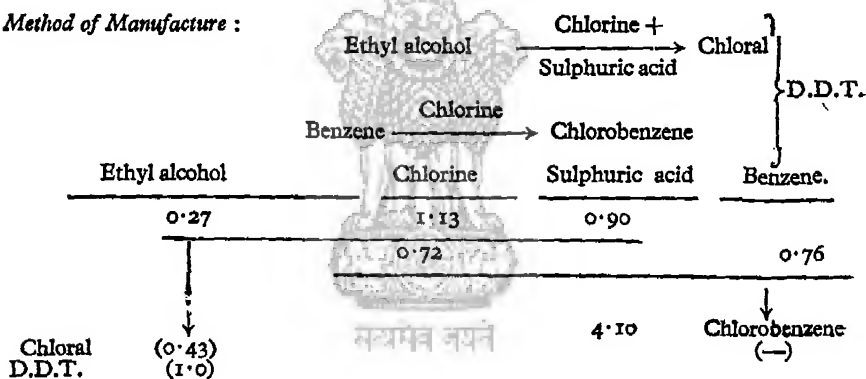


*Total Basic Raw Materials Required.*

	Benzene.	Chlorine.
(a) For 1 lb. of B.H.C.]	0.26	0.72
(b) For 44,80,300 lbs. of B.H.C. [11,64,800		32,25,600

## 31. D. D. T.]

*Method of Manufacture :*



*Total Basic Raw Materials Required.*

*Starting from Ethyl alcohol and benzene*

(a) for 1 lb. of D. D. T.]

Ethyl alcohol			
0.27	1.85	5.0	0.76
(b) for 1,34,40,000 lbs of D. D. T.			
36,28,800	2,48,64,000	6,72,00,000	1,02,14,400
Starting from Chloral			

(a) for 1 lb. of D. D. T.

Chloral.	Chlorine	Benzene	Sulphuric acid
(0.43)	0.72	0.76	4.10
for 1,34,40,000 lbs of D. D. T.			
57,79,200	96,76,800	1,02,14,400	5,51,04,000

## APPENDIX No. 9

### SUMMARY OF RECOMMENDATIONS OF THE REPORT OF THE COMMITTEE (MASANI COMMITTEE) FOR THE IMPROVEMENT OF SLAUGHTER HOUSES IN THE STATE OF BOMBAY (APPOINTED BY THE GOVERNMENT OF BOMBAY BY THEIR RESOLUTION IN THE LOCAL-SELF GOVERNMENT AND PUBLIC HEALTH DEPARTMENT No. 6689/33, DATED THE 10TH JANUARY, 1951.)

#### *Existing Condition of Slaughter Houses in Bombay State*

1. Standard plans of different kinds of slaughter houses for towns of varying sizes should be got prepared either by the Public Health Engineer to Government or by some Special Engineer and these plans may be commended to local bodies for adoption.

2. The Public Health Authorities should see that the necessary measures in regard to drainage, water supply, lighting and ventilation and general hygiene are adopted at all slaughter houses.

3. Slaughter houses should be properly equipped and their working properly supervised.

#### *Location and Administration of Slaughter Houses*

4. Even if slaughter houses are modernised, they should not be located in the midst of or in close proximity to towns and cities.

5. Slaughter houses should, as far as possible, be outside inhabited areas but within a reasonable distance of them to facilitate transport and marketing.

6. The sites selected for slaughter houses should not be on low-lying ground, and should as far as possible, be in close proximity to adequate sources of water supply and within a short distance of a railway line or public thoroughfare.

7. The present structures at Bandra should be demolished and a new slaughter house for the city of Bombay may be erected as contemplated either, at Deonar or at Thana.

8. As a rule no private slaughter houses should be allowed except perhaps in small villages outside the Village Panchayat areas, they should also however be subject to licence and proper regulation.

9. The slaughter houses in the State should be run by local bodies in the interest of public health and hygiene and in order to facilitate, wherever possible, proper meat inspection.

10. There should, as far as possible, be only one slaughter house properly constructed and managed in each town.

11. Two or more small towns or villages within a reasonable distance of one another may be permitted or encouraged to have a common slaughter house.



12. Where conditions appear favourable, the question of establishing regional slaughter houses may be examined by Government and local bodies concerned.

#### *Prevention of Slaughter of Useful Cattle*

13. The existing restrictions and vigilance in regard to the slaughter of useful animals may continue. There is no case for making these restrictions more stringent.

#### *Production and Preparation of Meat*

14. Slaughtering should be done only at fixed hours so as to admit of adequate supervision and inspection and also to facilitate the cleaning of slaughter houses premises. It should, however, be left to the local bodies to choose the time subject to the principles laid down.

15. Cold storage arrangements should be made at the markets rather than at the slaughter houses. Only in Bombay, Ahmedabad, Poona and Sholapur are cold storage arrangements necessary at the slaughter houses for the preservation of glands and internal organs required for medicinal purposes.

16. Cattle should be rested and watered before slaughter.

#### *Meat Inspection*

17. An efficient system of meat inspection is necessary and facilities for both ante-mortem and post-mortem examinations should be provided.

18. The work of meat inspection should be entrusted to veterinary officers or, after necessary training, to sanitary inspectors.

19. A special course in meat inspection may be instituted for sanitary inspectors at the Bombay Veterinary College.

20. The reasons for and circumstances leading to the limited output of veterinarians from the Bombay Veterinary College may be examined and, if possible, rectified.

21. In order to secure uniformity in meat inspection regulations throughout the State, the Animal Husbandry and Veterinary Science Department may be asked to draw up a code of judgments for the guidance of meat inspectors.

22. Government should undertake special legislation to make it obligatory on the part of local bodies to institute proper meat inspection at the slaughter houses under their control by employing trained staff.

#### *Training of Staff at Slaughter Houses*

23. The butchers and flayers employed at slaughter houses in connection with the slaughtering of animals may be made to undergo certain training so that they can be made aware of the defects in flaying and other auxiliary operations and possess elementary knowledge of anatomy and the hygienic handling of meat. They may also need to be trained in the use of modern methods of slaughtering if these are introduced.

24. The Licensing Authority should see that licences are given only to those who possess the required knowledge and that the licences of those who do not satisfy this condition or who infringe the conditions of the licence should be cancelled.

25. Requisite training may be given at slaughter houses in the local languages either by the head butchers under the supervision of Veterinary Officers or by the Veterinary Officers, themselves.

#### *Transport and Handling of Meat*

26. Vehicles used for transport of meat should be capable of being cleaned easily and thoroughly. For this purpose, the meat vans should be made of metal or metal-lined bodies. During transport, the meat should not be exposed to public view or dust or flies, and the vans should be adequately ventilated.

27. Meat transported by head-loads, or on bicycles, etc. should be conveyed in closed metal containers.

28. Provision of refrigerated means of transport is not necessary except in rare cases.

29. Regulations may be made regarding proper transport of meat.

#### *Marketing and Sale of Meat*

30. Cold storage arrangements are required at the markets to avoid deterioration and putrefaction of meat.

31. Meat markets require to be remodelled according to modern sanitary standards and fitted with up-to-date equipment. Standard type of designs of market buildings may be drawn up.

32. Meat should be allowed to be sold only in Municipal Markets. Private markets and shops for selling mutton and beef should be discouraged.

33. Local bodies may adopt suggestions made and lay down rules and regulations for the control of meat stalls.

#### *Utilisation of Internal Organs and Glands for Manufacture of Biological Products*

34. Proper collection and preservation of glands and organs is possible only in those slaughter houses where the number of animals slaughtered is at least 500 a day and where cold storage facilities at a temperature of  $-15^{\circ}\text{C}$  can be provided.

35. Facilities on the lines indicated in Dr. Nandi's note may be provided if the parties concerned come to an understanding as regards slaughter and removal of glands.

36. The authorities of the slaughter houses should formulate a suitable scheme in consultation with the parties concerned.

#### *Utilisation of Slaughter House Waste and By-products*

37 and 38. In order to make sufficient quantities of waste products available for processing on a profitable basis, centralisation of slaughter in a modern slaughter house is essential. Installation of processing plants near large slaughter houses is essential for the utilisation of waste products.

39. The utilisation and processing of slaughter house residues may preferably be left to private agencies as this is entirely a commercial proposition. Local bodies should only provide facilities for collection and storage of the material required.

40. A suitable person may be deputed for training overseas to make a special study of the modern methods of processing slaughter house wastes.

#### *Flaying*

41. The main remedy for removing defects in flaying lies in the expansion of slaughter houses and provision of more space to each butcher to carry on his operations freely.

42. As soon as animals are received into a slaughter house, they should be well washed and cleaned.

43. Sale of hides and skins by forward contracts should be banned.

#### *Legislation*

44. The location, construction and management of slaughter houses should be regulated by rules drawn up for the purpose.

45. No slaughter house may be allowed to be constructed by a local Body unless permission is obtained from the Director of Local Authorities who will consult the other officers concerned as to the suitability of the site and the proposed buildings.

46. The existing slaughter houses which do not come up to the minimum requirements laid down may be demolished.

47. Government may make suitable contribution towards the cost of construction or remodelling of slaughter houses.

#### (EXTRACTS FROM THE NOTE ON ANIMAL GLANDS AND ORGANS.)

BY

DR. B. K. NANDI

\* \* \* \*

The glands and organs can be collected from slaughter houses. Some of them, such as, the liver, spleen, heart and testes are even now collected by interested parties from slaughter-houses within a reasonable time after the animals are slaughtered, and carried to their respective places in their own transport, cooled in ice, and kept overnight in cold storage. As these glands and organs do not deteriorate within half an hour after the animals are slaughtered, there is not much difficulty in their collection and effective utilisation.

Stomachs also can be collected easily under the present conditions, although there is still scope for improvement on the time factor for collecting them.

However, enormous difficulties are experienced in the collection of the smaller glands such as pancreas, suprarenals, ovaries, thyroid, para-thyroid, thymus and pituitaries. The main difficulty lies in the long delay involved in making these glands available for

freezing within half an hour of killing the animals. These glands have active hormones which begin to deteriorate by a process of self-autolysis at ordinary atmospheric temperature after about half an hour of killing an animal. Sometimes, as much as 75 per cent. of the hormones deteriorate if this time factor is ignored. It is, therefore, absolutely essential that arrangements should be made in the slaughter-houses by which these glands can be taken out of the body for freezing purpose within a maximum space of half an hour after the animals are killed.

Under conditions prevailing in the slaughter-houses at present, far too much time is taken to flay the animals after they are killed. It often happens that an hour and a half elapses between killing and the flaying and opening of the stomach.

This results in the glands becoming useless from the pharmaceutical point of view, and they can at best be utilised only as accompaniments to flesh for purposes of food.

*The time-factor and collection.*—I have gone carefully and in great detail together with butcher-owners into this perplexing problem of time factor between killing, and flaying and opening of the stomach for collection of glands. As stated above, no proper attention has been paid hitherto to this very important point of correlating the time of killing with that of flaying.

*Suggestions for Improvement.*—In order to bring the slaughtering work in line with the later processes, it will be necessary to divide the slaughtering into four shifts of two hours each, say from 4 to 6 P.M., from 6 to 8 P.M., from 8 to 10 P.M., and from 10 P.M. to midnight. 720 animals will be slaughtered in each shift of two hours.

*Slaughter House for sheep.*—1. Number of lethal chambers to be provided (chambers for slaughtering) is 4.

Each lethal chamber will receive about 180 animals in two hour's time, and their killing will be regulated in such a way that dumping of the animals on the floor or jamming of the conveyor pulleys will not be permitted. The slaughtering will be distributed evenly over the full two hours' time.

2. Each lethal chamber should have six conveyor pulley hooks diverging from the lethal chamber into the flaying hall. These conveyor pulleys should be of the overhead type, fitted with hooks on which to hang the carcasses. Thus, there should be a total of 24 conveyor pulley hooks for the four lethal chambers.

*N.B.*—In a new slaughter-house, provision must be made to enable an increase in the number of animals slaughtered and flayed by at least 50 per cent.

3. Each conveyor pulley hook should be fed with 30 carcasses for flaying at periodical intervals within two hours' time.

4. At the end of each conveyor pulley hook, there will be one man for flaying, and one man for removing the internal organs and glands. Thus, each lethal chamber will be served by 6 flayers and 6 gland-removers.

N.B.—Arrangements will have to be made for hooks to be placed overhead in the flaying hall, on which to hang the flayed carcasses, in order to prevent their being dumped on the floor and their jamming up the hall.

On the above basis:—

Number of flayers in one shift will be	24
Flaying of each sheep by a man	} will take 4 minutes.
Removal of internal organs and glands by a man	
The number of sheep that will be flayed by 24 men every 4 minutes will be	24
Number of animals taken up for slaughtering, flaying and removal of internal organs and glands in two hours time.	720

NOTE.—In each lethal chamber, only six animals should be killed every four minutes.

Thus, in eight hours' time, at this rate and under the arrangements suggested above, 2,880 animals can be slaughtered and flayed, etc., to enable the glands to be taken out within half an hour of killing each and every animal.

In order to provide the rest necessary for the flayers, arrangements should be made whereby the first shift man will work in the third shift, and the second shift man will work in the fourth shift.

This arrangement up to the stage where glands are removed is regulated mechanically like clock work.

*Collection of Glands for freezing.*—One man should be put with each batch of six flayers attached to each lethal chamber, for the job of gathering the glands and putting the essential ones in the freezing storage.

Glands and internal organs like liver, spleen, testes, ovaries, heart, stomach, and gall bladder and bile can be removed and kept on one side without freezing, and supplied by the owners to their respective customers.

Glands like pancreas, suprarenal, thyroid, para-thyroid, thymus, pituitary must be taken out and put into special containers on another side. These containers will have to be supplied by slaughter-house authorities and maintained at their expense.

As indicated above, the gland gatherer attached to each lethal chamber will gather these latter glands from the gland-removers, immediately they are removed, and hand them to the Inspectors who will take charge of them and put them in the central freezing cabiner maintained at the expense of the authorities. These glands can be sold the next day to interested manufacturers.

One Inspector and four men are necessary for gathering these glands for every 720 animals in a shift. As they will also work in two alternate shifts, they can handle 1,440 sheep per day, or half the number of animals every day. Therefore, a total number of two inspectors and 8 men will be sufficient for the four shifts together.

This brings us to the following number of personnel for the four shifts to handle 2,880 sheep:—

Two inspectors, 48 flayers, 48 men to remove organs and glands, 8 butchers and 8 handymen for butchers (one of each in a lethal chamber per shift) and 8 gland-gatherers.

*Special arrangement for the collection of pituitary glands from the heads of cattle.*—It was observed that one worker can remove the pituitary glands from the head of a cow or buffalo by splitting open the head in about 7½ minutes' time. The conveyor pulleys will supply eight heads per hour, and one man should be able to split these 8 heads and take out the pituitary glands from them. On this basis, the nine conveyor pulleys will require five men for this special work.

One man will be required to gather the pituitary glands and to hand them over to the Inspector.

Thus, to collect the pituitary glands alone, the additional personnel required will be:—

Men to split open the head of cattle	...	5
Gland-gatherer	...	1

*Economics.*—The larger glands and organs like liver, spleen, heart and testes are being sold at prices, highly profitable to the butchers, even now, as there is a consistent demand for these from pharmaceutical manufacturers. There is not much demand, however, for stomachs at present time, as nobody manufactures pepsin in this country. But these organs are being sold as cheap food material to a negligible extent.

A system by which employees engaged in slaughtering, flaying, collection of glands and depositing them in the freezing storage, etc., can be paid from a common pool fund of a co-operative character, will have to be devised. The owner-butcher will pay at the end of each week into the pool amounts of money calculated on the basis of the number of animals serviced by all the employees engaged on this work, and bulk payment on a *pro rata* basis will be paid by the co-operative pool. This pool should also bear the Municipality's expenses in connection with salaries of the Inspectors, depreciation of the Freezing Chambers. The administrative details of the working of this scheme can be evolved by mutual consultation between the Health Department of the Municipal Corporation and the owner-butchers of the Slaughter House.

All the bile from sheep and cows and buffaloes should be collected and kept in the cold storage. There will be parties who will exploit this valuable matter for manufacture of bile salts which have important medicinal uses. A fairly handsome revenue can be obtained from its sale.

As regards pituitary glands from the heads of sheep, firstly, it is a difficult task to get the glands from inside thousands of heads, secondly, the butchers state that once the head is split open to remove the gland in the slaughter house, the value of the head diminishes in the market owing to unaccountable prejudice on the part of the purchasing public. It is, however, urged that in future suitable devices should be adopted to get this master-gland out of the heads of sheep in active condition.

## APPENDIX NO. 10

### LIST OF ESSENTIAL DRUGS, INSECTICIDES, ANTIBIOTICS, DISINFECTANTS AND MEDICINAL FOODS WHOSE PRODUCTION SHOULD BE ENCOURAGED

#### (A) Antibiotics :

1. Penicillin—(Penicillin G. Sodium or Potassium Crystalline, Penicillin calcium, Penicillin Procaine G. (Vety) cerate, Penicillin Procaine G in oil, Penicillin Procaine Aqueous)
2. Streptomycin (Streptomycin sulphate, Dihydro-streptomycin sulphate or Calcium chloride complex).
3. Chloramphenicol (Chloromycetin).
4. Chlorotetra-cyclin (Aureomycin).
5. Oxytetracyclin (Terramycin).
6. Erythramycin (Ilotycin).

#### (B) Sulpha Drugs :

7. Sulphanilamide.
8. N-3 : 4-Dimethyl Benzoyl Sulphanilamide (Irgafen).
9. Sulphathiazole.
10. Phthalyl Sulphathiazole (Thalazol).
11. Succinyl Sulphathiazole (Sulphasuxidine).
12. Sulphadiazine.
13. Sulfamethyl Diazine (Sulpha-merazine B.P.C.).
14. Sulphadimidina B. P. (Sulphamezathine).
15. Sulphafurazole (Gantrisin).
16. Sulphaguanidine.
17. Sulphacetamide (Albucid).
18. Phthalyl Sulphacetamide.

#### (C) Antimalarials :

19. Quinine and its salts
20. Chloroquin and its salts.
21. Proguanil Hydrochloride B. P. (Paludrine).

#### (D) Vitamins :

22. Shark Liver Oil.
23. Nicotinic acid and amide.
24. Vitamin 'A'.
25. Vitamin B Complex.
26. Vitamin B<sub>1</sub> (Thiamine Chloride or hydrochloride).
27. Vitamin B<sub>2</sub> (Riboflavin).

28. Vitamin B<sub>6</sub> (Pyridoxine).
29. Vitamin B<sub>12</sub> (Cyanoco balamine).
30. Pantothenic acid.
31. Folic acid.
32. Vitamin C (Ascorbic acid).
33. Vitamin D.
34. Vitamin E ( $\alpha$ ,  $\beta$ ,  $\gamma$ , -Tocopherol).
35. Vitamin K. (Menophthionum B. P.)
36. Vitamin P. (Rutin).
37. Multivitamin preparations and Yeast preparations.

(E) *Endocrines* :

38. Insulin and preparations thereof, (*viz.*, globin insulin, protamine zinc insulin, N. P. H. insulin, Insulin Lente).
39. Thyroid.
40. Injectio Pituitri Posterioris B. P. (Pituitrin).
41. Injectio Oxytocini B. P. (Pitocin).
42. Injectio Vasopressini B. P. (Pitressin).
43. Adrenaline and salts.
44. Follicular Hormone (Organic and synthetic).
45. Luteal Hormone.
46. Testosterone Propionate.
47. Adrenal cortical hormones (Organic and Synthetic, DOCA, ACTH, Cortisone).
48. Oestrodial B. P. C. or equivalent (Diethyl Oestradiol).

(F) *Haematinics* :

49. Crude Liver Extract.
50. I. V. Iron.
51. Ferrous Gluconate.

(G) *Anti-Coagulants* :

52. Heparin.
53. Dicoumaral B. P. C.
54. Ethyl Biscoum Acetate (Tromexan).

(H) *Coagulants* :

55. Hemostatistics derived from Bovine blood (Coagulin (Ciba), Hemoplastin).
56. Congo, Red.
57. Russels' Viper Venom.
58. Spongia Gelastine Absorbenda B. P. C. (Spongstan and Gelfoam).
59. Protamine Sulphas (Thrombin Tropical).



(I) *Diuretics :*

- 60. Mersalyl B. P. or Mercurial. Diuretics like "Neptal"
- 61. Mercaptomerin Sodium.
- 62. Theobromine Sodium Salicylate.

(J) *Anaesthetics and Analgesics:*

- 63. Barbiturates namely phenobarbitone, amilobarbitone, allo-barbitonum B. P. C., Butyl Ethyl barbituric acid.
- 64. Chloral hydrate.
- 65. Pethidine hydrochloridum B. P. with or without Hyoscine.
- 66. Caramipheni Hydrochloridum.
- 67. Phenytoin sodium.
- 68. Methoin.
- 69. Cinchocaine hydrochloride B. P.
- 70. Amylocaine Hydrochloride B. P. C. (Stovaine).
- 71. Ethyl chloride.
- 72. Procaine hydrochloride B. P.
- 73. Thiopentone sodium B. P.
- 74. Efocaine.
- 75. Bromethol B. P.
- 76. Benzamine Hydrochloride B. P. C.
- 77. Amethocaine hydrochloride B. P.
- 78. Benzocaine.
- 79. Paraldehyde—(Ampoules).
- 80. Perocaine Hydrochloride U. S. P.
- 81. Tubocurarine Chloride B. P. (Introcostrin).
- 82. Pentobarbitone sodium B. P.
- 83. Soda lime.
- 84. Mephenesin (Mephanesinum B. P. C.).
- 85. Cyclopropaine.
- 86. Trichloroethylene B. P.
- 87. Cocaina and Cocaine hydrochloride.
- 88. Ether Anaesthetic.
- 89. Chloroform Anaesthetic.
- 90. Opium and its alkaloids—Morphine, Aethyl morphine hydrochlor (Dionin), Diamorphine hydrochloride (Heroin), Inj. Morphinae, Codeine and its salts, Papavarine, Injectio Papavareti B. P. C. or equivalent.

(K) *Anti-Syphilitics :*

- 91. Diethyl amine Acetarsol.
- 92. Oxyphenarsine Hydrochloride B. P.
- 93. Neoarsphenamine B. P.
- 94. Injectio Bismuthi B. P.
- 95. Injectio Bismuthi Oxychloride B. P.
- 96. Fries Antigen.

97. Sulpharsphenamine B. P.

(L) *Anti-Leprosy :*

98. Promanide (Promin).

99. Solapsonum B. P. C. and derivatives.

100. Dapsonum—(DADPS) and derivatives.

(M) *Anti-Tuberculosis :*

101. Para-Amino-Salicylic Acid (PAS).

102. Isonicotinic acid hydrazide (Isoniazid).

(N) *Vaccines, Sera and Antitoxins :*

103. Prophylactic Vaccines for Diphtheria, Tetanus, Whooping cough, T. A. B. (Typhoid & Paratyphoid) Yellow fever, Cholera, Typhus, Plague.

104. Serum anti anthra cycum B. P. C.

105. Serum anti meningo Cocci.

106. Anti toxinum scarletinum B. P. C.

(O) *Drugs of Vegetable Origin :*

107. Quinidine Sulphate.

108. Ephedrine.

109. Caffein and its salts.

110. Strychnine.

111. Santonin.

112. Emetine hydrochloride.

113. Emetine Bismuth Iodide.

114. Rauwolfia Serpentina.

115. Digitalis leaf and alkaloids (Digoxin etc.).

116. Ouabin (Strophanthin G.)

117. Picrotoxin.

118. Ext. Kalmegh Liq.

119. Ext. Punarnava Liq.

120. Ext. Gokharu Liq.

(P) *Other Drugs :*

121. Sodium Cocodylate.

122. Ergomotrine.

123. Bismuth salts.

124. Calcium Gluconate.

125. Ergotamine Tartaras.

126. Glucose.

127. Mag. Trisilicate.

128. Ethyl iodophenyl Undecyclate.

129. Oleum Iodosatum B. P.

130. Pheniodol B. P. C.

131. Sodium Iodomethamus U. S. P.

132. Iodoxy-lum B. P.
133. Barium Sulphate and preparations thereof.
134. Pulvis Iodophthaleine Co. B. P. C.
135. Sodium Lactate.
136. Mag. Sulphate (50 per cent. and 25 per cent. ampoules).
137. Sodii Sulph (4·28 per cent. I. V.).
138. Protein Hydrolysate (for I. V. use).
139. Blood Plasma and substitutes (Dextran, Intradex & Plasmosan).
140. Antimony Sodium Thiosulphate (Inj.).
141. Urea Stibamine.
142. Diethyl Carbamazine citras Acidus.
143. Octinum (Knoll's).
144. Iodochlorhydroxyquinum.
145. Di-iodo-oxyquinoline.
146. Methionine or equivalent.
147. Methyl or Propyl-Thiouracil.
148. Hippuric acid.
149. Colloidal Iodine.
150. Anti-histamines (Antistine, anthisian Benadryl, histadyl Pyri benzamine etc.).
151. Histamine.
152. Hyaluronidase (Hyalase, Rondase).
153. Dimercaprol (B. A. L.).
154. Strepto Kinase and Strepto dornase.
155. Carbachol or equivalent.
156. Ethanolamine Oleate.
157. Neostigmine Bromide.
158. Neostigmine Methyl Sulphate.
159. Hexamethonium Bromide and Bi-tartarate.
160. Tetra ethyl Ammonium Bromide B. P. C.
161. Tolazolinae Hydrochloridum.
162. Labelin hydrochloride (Injections).
163. Nikethamide B. P. (Coramine) and combinations with Theophyllin and adenosine.
164. Leptazol B. P. or equivalent (Cardiazole).
165. Pholedrine Sulphas B. P. C. (Veritol).
166. Aminophylline (Cardophylline).
167. Amphetamine B. P.
168. Dexamphetamine Sulphas B. P. C.
169. Acetarsol B. P. C. (Stovarsol).
170. Carbarsone.
171. Acetyl Cholin.

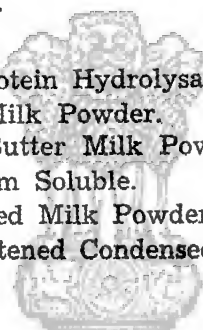
- 172. Aspirin.
- 173. Salicylic Acid.
- 174. Sodium Salicylate.
- 175. Phenacetin.
- 176. Chlorobutanol.
- 177. Hexamine.
- 178. Cinchophen.
- 179. Potassium iodide.
- 180. Argenti Proteinus.

**(Q) Insecticides, Antiseptics and Disinfectants :**

- 181. D. D. T.
- 182. B. H. C.
- 183. Dettol.
- 184. Dysol.
- 185. Mercurochrome or Acriflavine.
- 186. Phenyle.

**(R) Foods :**

- 187. Oral Protein Hydrolysate.
- 188. Dried Milk Powder.
- 189. Dried Butter Milk Powder (Eledon).
- 190. Caseinum Soluble.
- 191. Separated Milk Powder.
- 192. Unsweetened Condensed Milk.



सत्यमेव जयते



सत्यमेव जयते

## APPENDIX NO. 12A

### NOTES ON RESEARCHES CARRIED OUT UNDER THE AUSPICES OF THE COUNCIL OF SCIENTIFIC AND INDUSTRIAL RESEARCH

In 1940, a Committee named as "Pharmaceuticals and Drugs Research Committee" was constituted under the auspices of the Council of Scientific and Industrial Research. At the time of its constitution, the Committee was confronted, with the problem of shortages of essential drugs due to the war. The Committee, therefore, initiated a programme of work for overcoming the shortages and started investigations relating to (1) manufacture of synthetic drugs, like phenacetin, salversan, carbarsone and others, whose methods of preparation were well established; (2) natural drugs, like atropine, emetine, gallic acid and thymol from known sources, taking into account the scarcity of chemicals and solvents; (3) glandular products, like adrenaline, thyroxine and pituitrin, according to methods modified to suit Indian conditions, and (4) commercial exploitation of alkaloids of *Rauwolfia serpentina* and Kurchi bark, resin from bhilawan nuts, bitter constituents of nim and other indigenous plant products.

In 1944 the Committee decided to switch over from a programme of immediate *ad hoc* investigations to a planned programme of long range research to help the indigenous drug industry. A sub-Committee was appointed to prepare a planned programme of work to be circulated to university departments, research institutes and medical colleges.

The Sub-Committee also recommended the setting up of a Central Drug Research Institute, which was established in 1951. A brief note on this Institute is attached.

The Committee has under consideration the compilation of a monograph on the indigenous drugs of India. The First part of the work, entitled "Indian Pharmaceutical Codex", has been published. The "Glossary of Indian Medicinal Plants" by Col. R. N. Chopra, is under publication.

#### *Malaria Chemotherapy*

A Sub-Committee was set up by the Council in August 1948, to initiate researches on malaria chemotherapy. The Committee surveyed the status of our knowledge of antimalarial drugs in prophylactic, suppressive and clinical therapy and the relative merits of antimalarials, such as quinine, mepacrine, paludrine and chloroquin, in the treatment of malaria. The Committee concluded that quinine products still form the most important and effective remedy for the treatment of malaria. After considering in detail various aspects of production, consumption and cost of treatment with quinine and

other cinchona alkaloids as compared to synthetic antimalarials it was recommended that :

- (i) In order to encourage the use of quinine and other cinchona products and to maintain the existing plantations the Government of India may consider further reduction in the cost of quinine production so that the cost of treatment with cinchona alkaloids can compare with that of treatment with synthetic antimalarials ;
- (ii) In view of certain advantages of synthetic antimalarials over quinine and its products and the increasing demands for their use, the Government of India be approached to set up, as early as possible, a plant for the manufacture of synthetic antimalarials of the group—4 amino-quinoline such as chloroquine and the necessary intermediates.

The Committee has initiated research on screening of anti-malarial preparations synthesized in various laboratories in India. Studies have been undertaken on the metabolism of host, drug and parasite with particular reference to Indian strains and biochemical changes in the host following the attack of malaria. These investigations are in progress at the Malaria Institute of India, Delhi, Bengal Immunity Research Laboratory, Calcutta and the School of Tropical Medicine, Calcutta.

At the suggestion of the Committee, statistical analysis is being made of the data collected from therapeutic trials of antimalarial drugs under the Director-General, Armed Forces, Medical Services.

Trials on drugs which have been claimed to prevent malaria relapses have been undertaken in two areas, one in which intensive control has been effected by the use of D.D.T. and another, in the centre of hills, where there has been no fresh infection—to obtain a correct appraisal of the effectiveness of a particular drug or a combination of drugs in prevailing relapse.

### *Pharmacological Research*

The Pharmaceuticals and Drugs Research Committee after drawing attention to the paucity of facilities and personnel for pharmacological work, has recommended measures for the training of pharmacologists. A Sub-Committee was constituted (1) to survey the pharmacological work carried out in India and to suggest ways and means for encouraging pharmacological and biological research of fundamental and applied character; (2) to review the present position of indigenous drugs industry; and (3) to explore the possibilities of developing farms for laboratory animals. The Committee recommended that (a) intensive efforts should be made to develop the production of antibiotics and other synthetic remedies; (b) drugs research in India should be directed towards the discovery of new antibiotics and other synthetic remedies; (c) drug research in India should be directed towards the discovery of new antibiotics from indigenous sources; (d) a chemotherapeutic approach should be made towards the treatment of diseases common in India such as malaria, tuberculosis, leprosy, cancer and gastro-intestinal disturbances; and

(e) to achieve this objective it is essential that coaltar intermediates and calcium carbide industries should be developed as early as possible. At the instance of the Committee, the Council has under consideration the starting of a journal of Biological Sciences. A microbiological centre has been set up at St. Xavier's College for studies on natural and synthetic antibiotic substances.

An insecticide testing centre has been established at the Malarial Institute, Delhi for testing insecticides developed under the research schemes sponsored by the Council.

### *Research Projects*

A brief review of the research schemes sponsored and worked under the purview of this Research Committee is given below:

#### *1. Research on plant constituents—Dr. S. Siddiqui, Delhi.*

(a) Investigations on chana (*Cicer arietinum*) led to the isolation of three crystalline constituents, provisionally named Biochanin A, Biochanin B, and Biochanin C. Biochanin A was identified as a derivative of phenyl coumarin. This was the first substituted coumarin to be isolated from a natural product.

Further investigations revealed that Biochanin B had the characteristics of an amine acid. Biochanin B was definitely related to Biochanin A.

(b) *Psoralea corylifolia*—A new crystalline lactone, provisionally named psoralidin, was isolated from the pericarp of the seeds. Analytical data indicated that it was a furocoumarin with a phenolic hydroxyl group and an isoprene chain attached to the benzene ring.

(c) *Allium sativum*—A highly active (antibiotic) concentrate has been prepared in 0.4 per cent. yield.

(d) *Rauwolfia serpentina* Benth.—A series of 5 crystalline alkaloids were isolated from the root bark of *R. serpentina*. Clinical observations have established their utility in the treatment of chronic insomnia, insanity and hysteria.

An assay method was finalised for inclusion in the Indian Pharmacopoeial List.

(e) Chaksu seeds—Two water soluble insomeric alkaloids were isolated and their values as therapeutic agents were investigated.

(f) *Stephania glabra* Lour.—Two colourless crystalline alkaloids were isolated. The main alkaloid (2.5 per cent.), forms an insoluble iodide and the other (0.5 per cent.), a soluble iodide. The alkaloids were toxic to frogs and their toxicity increased by methylation.

(g) *Saussurea lappa*—The active principles of the plant were resinous in character and no alkaloid appeared to be present.

(h) Mango blossoms—The blossoms contain 15 per cent. tannin on the weight of the air-dried materials. Gallic acid was isolated in 89 per cent. yield from aqueous extracts.

#### *2. Investigations on nim—Dr. S. Siddiqui, Delhi.*



The main bitter constituent of the nim bark is nimbidin. Clinical trials showed that nimbidin was efficacious in the treatment of a variety of skin affections. An emulsion of nimbidin may be used as a gargle in sore throat.

A new crystalline bitter constituent identical with nimbidin was isolated from the nim root bark. The pericarp of nim seed yielded a crystalline neutral non-bitter compound.

Various degradation products of nimbidin were obtained by the action of halogen acids, zinc distillation and alkali fusion.

Different metallic salts of nimbidinic acid and salts of quinine with nimbidin and nimbidinic acid were prepared. Nim blossoms contain an essential (0.5 per cent.); flavone (m.p. 272°C.), a sterol glucoside (m.p. 294°C.); a sterol (m.p. 137°C.), a neutral crystalline product (m.p. 69°C.); and fatty acids.

The petrol ether insoluble fraction of ethereal extract of nim leaves yielded a water insoluble amorphous bitter substance (yield, 0.6 per cent. on the wt. of fresh leaves) of an acid character melting at 90-100°C.

### 3. *Antimalarial and antidyenteric drugs*—Dr. S. Siddiqui, Delhi.

(a) *Alstonia scholaris*—Preliminary investigations of alstonia bark yielded 0.9 per cent. alkaloids on the weight of the dry bark.

(b) *Holarrhena febrifuga*—East African samples of *H. Febrifuga* bark showed the presence of alkaloids similar to those isolated from the Indian kurchi bark.

Studies in the constitution of kurchi alkaloids gave interesting results. Distillation of tetramethyl holarrhimine yielded a crystalline base.

(c) *Picorrhiza kurroa*—Chemical examination of the drug resulted in the isolation of a bitter glycoside from the alcoholic extract of the drug. Two non-bitter crystalline compounds melting at 160°C. and 75°C. were also isolated.

(d) *Vitex peduncularis*—Two crystalline substances, melting at 155°C. and 280°C., have been identified in the neutral fraction. Vitenin, which was previously reported, appears to be therapeutically inactive.

(e) *Tinospora cordifolia*—Two crystalline bitter principles melting at 235°C. and 211°C. were isolated.

### 4. *Pyrethrum and its substitutes*—Dr. S. Siddiqui, Delhi.

A concentrated emulsion of pyrethrum extract was prepared which could be diluted with water and used as an insecticidal spray. One part of the emulsifier with 2 parts of Pyrocode 20 can be diluted to 200 parts with water to yield an effective spray. This was found to be more economical in use than any imported product.

Cold percolation of pyrethrum with cheaper solvents available in India gave an extract containing 10-15 per cent. pyrethrins. An economic process for the extraction of pyrethrin was developed.

Pyrethrum extracts can be stabilized with bhilawanol derivatives. A biologically stable, semi-vanishing, mosquito-repellant cream was prepared. Tests at the Malaria Institute of India showed that the cream was effective as a mosquito repellent. Work was undertaken to stabilise creams against breakage due to transport shocks during hot weather and processes were developed for the reclamation of broken creams.

Investigations on the subsidiary constituents of pyrethrum flowers revealed the presence of a carotenoid pigment. In attempts to isolate the irritant factor in pyrethrum, a number of phenolic fractions were separated and purified.

5. *Kakra singhi, brahmi and brahmi-mumduki*—Dr. Karimullah, Delhi.

Two crystalline products identified as *pix polyterpene* alcohols were obtained from *Kakra singhi*.

A glucoside was obtained from the alcoholic extract of *brahmi-man-duki*. Mannitol was isolated from *brahmi*, the whole plant being used in the investigations.

6. *Polyhydric alcohols from sugars*—Dr. Karimullah and Dr. Lal C. Verman, Delhi.

Sorbitol was separated as its pyridine complex and the yield quantitatively estimated. Chemically pure lead was found to be the best cathode material in the electrolytic reduction of sugars.

7. *Organo-arsenical compounds*—Dr. P. C. Guha, Bangalore.

Methods for the preparation of sulpharsphenamine and neorsphenamine from 3-nitro-4-hydroxy phenyl arsenic acid were studied and working conditions for the best recovery yields was established.

8. *Synthetic adrenaline*—Dr. P. C. Guha, Bangalore.

Experimental conditions for the reduction of adrenalone to adrenaline in economic yield, both by aluminium amalgam and by catalytic reduction with Raney nickel, and for the resolution of adrenaline have been investigated.

9. *Preparation of enterovioform*—Dr. P. C. Mitter, Calcutta.

5 An improved method for the preparation of 5-chloro-8-oxyquinoline was worked out. Iodination of this substance gave enterioform, 5-chloroiodo-8-oxyquinoline. But the yields were unsatisfactory.

10. *Preparation of novocaine*—Dr. P. C. Guha, Bangalore.

The scheme was sponsored during the war time with a view to develop a process for the preparation of novocaine from raw materials available in India, viz., alcohol, toluene and aniline.

Starting with toluene, the acetyl derivative of novocaine was prepared. The yield, however, was poor (30 per cent.).

11. *Optically active and racemic compounds*: (a) *Chemical*—Dr. Bawa Kartar Singh, Lahore. (b) *Pharmacological*—Dr. B. Mukherji, Calcutta.

d,1, dl-camphor Beta-sulphonates of 2-aminopyridine were tested for their pharmacological properties. It was not possible to establish the differential behaviour of optically active isomers on the basis of pharmacological, bacteriological and chemotherapeutic properties.

12. *Penicillin and other antibiotics*—Dr. V. Subrahmanyam, Bangalore.

More than 200 plants and two fungi were studied for the presence of antibiotics. Active agents, which were found to inhibit pathogens, were isolated from the following; *Plumbago zeylanicum*, *Carica papaya*, *Allium sativum*. *Moringa pterygosperma* and *Aristolochia indica*.

Allicin from garlic and pterygospermin from *Pterygosperma* possessed remarkably high antibacterial properties. Both were unstable and the former was toxic.

While allicin acted by the inhibition of active SH groups of enzymes, pterygospermin was not activated by SH reagents.

As pterygospermin exhibited a remarkable degree of synergism with penicillin and streptomycin, it might prove useful in bacterial infection, either alone or in combination.

Groundnut cake and wheat bran digests, particularly with additions of glucose and sodium chloride, provided suitable media for the production of streptomycin by *S. griseus*. Definite conclusions were obtained on the factors affecting the efficiency of the media.

13. *Preparation of glandular products and utilisation of shark waste*—Dr. B. B. Dey, Madras.

A procedure for the large scale production of adrenaline was standardised. Conditions for ampouling adrenaline preparations were studied and the potency tested pharmacologically. Storage conditions for overcoming the instability of adrenaline were also established.

Pituitrin—Conditions for large scale collection and desiccation of the posterior lobe of the pituitary were standardised. The potency of the preparations obtained conformed to the international standard. Active preparations were obtained from the anterior lobe of beef pituitary.

Thyroxine—Thyroxine was isolated in crystalline form in good yield and conditions for the large scale production of thyroxine and thyroid extracts were standardised. Local animals were observed to have unusually high organic iodine and thyroxine contents and the glands did not exhibit any seasonal variation.

The barium hydroxide insoluble portion obtained during the processing of desiccated thyroid could be processed for the isolation of thyroxine.

Insulin—Insulin was isolated from beef pancreas and the process for obtaining crystalline insulin—yield 10 mg. per kilogram of beef pancreas—was standardised.

Amino acids—The following amino acids were estimated in glue prepared from shark fins—arginine, 7.85; l-proline, 9.92; hydroxy-proline, 11.5; glycine, 21.15; and tyrocine, 1.02 per cent.

The residue left after extracting the oil from the liver was found to show antianaemic activity.

14. *Survey cultivation and improvement of medicinal plants—Col. R. N. Chopra, Jammu-Srinagar.*

Indian medicinal plants have been classified under the following categories: (a) plants recognised in British Pharmacopoeia and their substitutes in India; (b) plants recognised in British Pharmaceutical Codex and their substitutes in India; (c) medicinal plants used in indigenous systems of medicine.

In the survey of economic plants growing in Kashmir more than 500 species have been identified and added to the herbarium.

A survey of 'Plants recognised in the British Pharmacopoeia and their substitutes growing in India', Part I has been published.

Several crude drugs used in Indian medicine were collected from the market and examined for their purity and genuineness.

Seeds of plants of economic importance were imported from foreign countries for cultural trials. Some gave encouraging results.

A Glossary of Indian Medicinal Plants has been compiled.

15. *Cultivation and commercial development of medicinal plants (including insecticidal and insect-repellant group) of North Western Himalayan region—Col. R. N. Chopra, Jammu-Srinagar.*

A systematic survey and collection of medicinal, insecticidal and insect repellent plants, other economic plants and grasses and mushrooms was carried out at altitudes of 1,000—1,400 ft.

Cultivation studies on three plants, viz., *Glycyrrhiza glabra*, *Physochlaina praealta* and *Cassia angustifolia* and pyrethrum were carried out at different government nurseries (700—7,000 ft.) Subterranean portions of *G. Glabra* grown in the nurseries contained 3.5 per cent. glycyrrhizine as against 2—7 per cent. in the imported samples. Seeds procured from Australia are under cultural trials.

*Physochlaina praealta* cultivated in Srinagar contains 0.24—0.74 per cent. total alkaloids.

The herbarium contains more than 15,000 sheets, out of which 5,000 sheets have been arranged systematically and identified.

16. *Survey of economic plants of Ladakh—Col. R. N. Chopra, Jammu-Srinagar.*

The survey of this region (9,000—14,000 ft.) has revealed, the existence of several medicinal herbs which grow wild. They include: *Aretmesia ephedra*, *podophyllum* and aconite, besides many unknown drug plants used locally. *Physochlaina praealta* obtained from this region was found to be a rich source of atropine.

The survey of the flora of Nubra, Rupshe and Zanskar valleys has been taken up.

17. *Preparation of new antimalarials*—Dr. P. C. Guha, Bangalore.

A new method was discovered for the synthesis of substituted biguanides, similar to Paludrine, from dithiobiurets. A number of trisubstituted biguanides were prepared.

Out of the new compounds which have been tested pharmacologically,  $N^1N^6$ -disulphanilamide biguanide hydrochloride,  $N^1N^6$ -disulphadiazine biguanide hydrochloride and  $N^1N^5$ -disulphaguanidine biguanide hydrochloride have shown definite antimalarial activity, while two compounds,  $N$ -allyl,  $N^3$ -2 pyridyl guanidine acetate and  $N^1$ -sulphanilamide sulphadiazine biguanide hydrochloride have shown slight antimalarial activity.

18. *8-Aminoquinolines as possible antimalarials*—Dr. U. P. Basu, Calcutta.

8-Aminoquinolines are known to exert special antimalarial activity. About 100 compounds of this group were synthesised out of which the following have shown antimalarial activity. (1)  $N^1$ -(6-methoxy-8-quinolyl)- $N^3$ -p-sulphon-2-pyrimidyl amido phenyl guanidine hydrochloride, active against *Plasmodium gallinaceum* and can be tolerated in four times the effective dose.

(2) 7-Chloro-8-amino-2-methyl-4-(4'-hydroxy-3'-diethyl-aminomethyl) aniline quinoline; Active against both *P. gallinaceum* and *P. berghei*; can be tolerated at four times the effective dose.

(3) 7-Chloro-2-methyl-4-(4'-hydroxy-3'-diethylamine methyl) aniline quinoline: preliminary tests have indicated high efficacy.

A product in triazine series, possibly with suppressive antimalarial action, has been synthesised.

Studies on drug-parasite relationship were also undertaken under this scheme.

The scheme has been terminated with effect from the 28th February, 1953.

19. *Biological studies of malaria parasites*—Dr. U. P. Basu, Calcutta.

Enzymes of the tricarboxylic acid cycle (T.A.C.) were prepared from liver and the action of quinine, Pentaquin, Chloroquin and quinine on the enzyme preparations were studied.

These antimalarials substances inhibited the oxidation of pyruvate, the stage of inhibition being probably  $\alpha$ -ketoglutarate to succinate. The inhibition was partially reversed, by hydrogen sulphide indicating that the SH groups of the enzymes were involved in the inactivation. The drugs inhibited the  $\alpha$ -ketoglutarate to succinate step in competition with arsenite. They stimulated the enzyme activity at the succinate to fumarate step whereas arsenite retained the inhibitory action. Excepting the stimulation of the succinate to fumarate step all other observations were verified in the malarial parasite-enzyme system isolated from the blood of fowls infected with *P. gallinaceum*.

In the light of the policy of the Research Committee that work under its auspices should have an applied bias Dr. Basu has been requested to reorientate the scheme accordingly.

20. *Biological studies on malarial parasites*—Dr. R. N. Chowdhury, Calcutta.

The work was directed to: (a) study of the behaviour of malarial parasites in artificial whole blood media; and (b) studies of different factors influencing parasite growth in the host.

In cultural experiments with *P. berghei* using synthetic media the majority of the parasite rings developed to growing trophozoites and schizonts in 24 hours. Parasites were observed to survive upto 72 hours. *P. gallinaceum* were also found to survive upto 48 hours in whole blood media.

Administration of p-hydroxy benzoic acid or concentrated liver extract appeared to increase the intensity of infection of *P. berghei* as compared to milk, while starvation was observed to inhibit it.

Growth promoting factors, such as methionine, p-aminobenzoic acid, ascorbic acid, glucose and concentrated liver extract could not reverse the inhibitory action of starvation.

This scheme has been terminated with effect from the 28th February, 1954.

21. *Screening of antimalarials*—Col. Jaswant Singh, Delhi.

Some of the well-known antimalarials, like quinine, mepacrine, proguanil, chloroquine, amodiaquine, and primethamine were assayed and their minimum effective dose determined, along with the quinine equivalent of the five last named drugs. Penequine, Sulphadiazine and Proguanil were also assayed for casual prophylactic action.

Synthetic antimalarials received from four research institutions and laboratories were tested. Two of the 65 materials tested, showed activity against *P. gallinaceum* in avian hosts (chick).

22. *Bactericidal and fungicidal properties of some plants*—Dr. R. G. Modak, Poona.

Twenty-five plants were investigated for bactericidal and fungicidal properties against micro-organisms. *Fagonia arabica* and *Hamiltonia suaveolans* were active against *Staphylococcus aureus* and *Escherichia coli*, while *Acorus colamus* was effective against *Eberthella typhosa* and *B. dysentery* as well.

23. *Synthesis of citrinin and its analogues*—Dr. K. Venkataraman, Bombay.

The work was carried out in three parts: (a) biosynthesis of citrinin; (b) chemical synthesis of citrinin and its derivatives and analogues; and (c) study of the antibiotic activity and toxicity of the compounds synthesized.

Citrinin was prepared by the Timonin Rouott method using a culture of *Aspergillus candidus* in yields of about 1 g. citrinin per litre of the medium 3:5-Dihydroxy phenyl acetic acid and its derivatives were found useful as precursors. Acetate and citrate were also found to play an important role in the elaboration of citrinin.

A modified procedure for the preparation of the methyl ester of citrinin involving the use of dimethyl sulphate and sodium carbonate in dry acetone was developed. A yield of 4 per cent. was obtained.

The following intermediates for the synthesis of citrinin were proposed 4-methyl resorcinol 2-carboxylic acid, 4:6 dimethyl resorcinol, 3:5 dimethoxy phenyl ethyl alcohol.

The methyl derivative of citrinin was obtained in good yield by the orthoformate reaction. The hydrazide of 4-m-hexyl resorcinol-2-carboxylic acid was also prepared.

The ester of citrinin with dihydre citrinin aminoethyl chloride in solution was found to be more active than citrinin. Toxicity studies on ethyldiamine salt of citrinin and dihydrocitrinin and synergistic combinations of citrinin, sulphadiazine and the amide of hexyl resorcinol-2 carboxylic acid were undertaken.

*24. Survey of fungus flora in search of antibiotics—Dr. S. R. Bose, Calcutta.*

Extracts of 95 fungi have been screened for anti-bacterial activity against Gram-positive and Gram-negative organisms and classified as strongly positive, positive and weekly positive. Fungi of the first two categories were studied in detail.

*Daedalea microzona*, *Fusarium vasinfectum*, *Lentinus revelatus*, *L. praerigidus*, *Psalliota campestris*, *Flammula dilepis* and *Helminthosporium oryzae* have shown promising results as antibiotics. *Marasmius companella* contained two distinct active principles, one strongly thermo-labile and the other moderately so.

The non-toxicity of *Psalliota campestris*, an edible mushroom, was confirmed by experiments at the Central Drug Research Institute, Lucknow. Clinical studies of purified extracts of *P. campestris*, supplemented by oral administration of crude cultural media, have given encouraging results in severe typhoid cases.

Investigations on the yield of antibiotics from the fungi and the effect of varying the constituents of the media were also carried out. Addition of glucose and vitamin B<sub>1</sub> has been found conducive to the antibacterial activity of the fungi.

This scheme has been terminated. Final report is under examination.

*25. Chemical examination of Indian lichens and heartwoods for antibiotics—Dr. T. R. Seshadri, Delhi.*

Several samples of lichens were collected, identified and their active principles isolated for pharmacological tests. Indian samples of *Parmelia* lichens were found to contain lichexanthone. *Usnea longissima* contained high percentage of usnic acid and barbatic acid, both of which are powerful antibiotics.

In view of the toxic character of usmic acid, its hydrazine hydrate has been prepared for tests.

Extracts of heartwoods of *Oaesalpinia* (Sappan wood) and *Cupressus torulosa* have also been studied. Brazilin, extracted from sappan heartwood by a new method, gave promise as antibiotic and

anti-tubercular in tests carried out at the Antibiotic Research Centre, Bombay. A new compound of tropalone nature was extracted from Cupressus wood.

26. *Synthesis of chloramphenicol (Chloromycetin), its derivatives and analogues*—Dr. B. D. Tilak, Bombay.

This investigation was taken up with the object of developing new methods of synthesis of chloramphenicol and its hydroxy and methoxy derivatives, with substituents in the m-position. Some success was achieved in obtaining intermediates.

New paths to chloramphenicol—Dr. A. Tyabji, Bombay.

The reaction of ammonia with phenylglyceric acid and with chloro and bromohydrine of cinnamic acid was reinvestigated. In all cases phenylisoserine is formed. This has been confirmed by comparison with phenylisoserine and its copper salt prepared by an unambiguous method.

27. *Antibiotic Research Centre*—Col. S. S. Bhatnagar, Bombay.

About 46 plants including 12 ferns have been screened for antibacterial activity.

*Pristimera indica* and *P. grahami*—The crystalline product isolated from the root bark of *Pristimera* has shown considerable bacterial titre against gram-positive, particularly the viridans group, and also against *Streptococcus faecalis*. *Pristimerin* has now been accepted as an antibiotic by the World Health Organisation.

*P. grahami* was also shown to be active against Gram-positive cocci. An economic method of isolation of dulcitol from plants belonging to Celastraceae species was developed.

The active principle isolated from *Gymnosporia rothiana* was found to be active against Gram-positive organisms.

Two alkaloids isolated from plant No. 25, though toxic, had marked influence on peristaltic movements of the intestines.

Active principles of a number of plants including *S. callosus*, *Embelia Robusta* and *Allium sativum* have also given promise of antibacterial activity.

Antibiotics from soil fungi—About 30 samples of Indian soils were screened for antibiotic producing fungi.

Out of the six fungi tested so far, two have shown action against *Staphylococcus aureus*.

28. *Microbiological Research Centre*—Col. S. S. Bhatnagar, Bombay.

The following substances were examined for their bactericidal and bacteriostatic properties; (a) substances isolated from Indian Lichens Usnic acid, barbatic acid, atrononin, rocellic acid (sodium salt) lichexanthone, thelophoric acid and salazinic acid; (b) synthetic compounds: 7-hydroxy-4-methoxy styryl coumarin, 3-para-nitro phenylcoumarin, acetone quinone complex I and II; and (c) heartwood



extract (Brazilin). Usnic acid showed both bactericidal and bacteriostatic action, but it is toxic. Rocellic acid (sodium salt) and the lephoric acid exhibited light antibacterial activity. Brazilin showed strong antibacterial action against ten micro-organisms as well as tubercular organisms. Quinone complex I exhibited a wide antibacterial spectrum. It is particularly active against *Vibrio cholerae*. The toxicity by the oral route is low.

29. *Synthesis of new types of insecticides*—Dr. T. R. Seshadri, Delhi.

A number of substituted coumarins were synthesized and tested for insecticidal properties. 3- and 4-phenyl substituted umbelliferones were found to possess insecticidal properties. Umbelliferones and their methyl ethers were also found to be highly toxic to fish.

Synthesis of a number of 3-phenyl umbelliferones was carried out by the methods of Meerwein and Ogialore for testing their toxicity to fish.

A method was developed for synthesizing partial methyl esters for biological testing (Seshadri's method).

Two war time German patented insecticides, tetra-ethyl pyrophosphate and p-nitro-phenyl-diethyl phosphate, were synthesized and found to be stomach poisons. Diethyl phosphoric acid ester of 3-methyl umbelliferone was found to be active.

A patent has been taken on the method of preparation of tetra benzyl pyrophosphate.

The possibility of manufacture of T.E.P.P. is under examination in consultation with National Research Development Corporation.

30. *Biological assaying of insecticides*—Col. Jaswant Singh, Delhi.

This study involved a systematic evaluation and biological assay of insecticides synthesised in various research laboratories.

Thirty-two compounds received from different sources have been examined. Compounds which exhibited insecticidal properties against house flies and mosquitoes are: Tetraethyl pyrophosphate, diethyl phosphoric acid ester of 4-methyl umbelliferone, parathion (E-605), p-nitrophenyl-o-o diethyl phosphate and a toxaphene compound (60.5 per cent. chlorine); nicotine sulphate showed poor insecticidal properties.

31. *Synthesis of kelling, its isomers and related compounds* Dr. T. R. Seshadri, Delhi.

Chellol (m.p. 175-76°C) was synthesised from the glucoside which occurs along with kelling and visnagin in the fruits of *Ammi visnaga* in 50 per cent. yield. Nor-chellol was prepared by the demethylation of chellol, but the yield was only 5 per cent.

Seeds of *Ammi visnaga* were examined chemically for their constituents for comparison with *Ammi majus* L., a closely related plant of Egypt. *Ammi majus* is said to be an effective cure for leucoderma. Xanthotoxin (m.p. 147-48°C) has been obtained 0.7 per cent. yield. Other constituents are under investigation.

An improved method for the synthesis of two compounds, 2-methyl-5:8-dimethoxy chromone and 2-isopropyl-5:3-dimethoxy chromone, both of which possess kellin-like activity on the coronary vessels of the heart was developed.

32. *Chemical and pharmacological examination of reputed cardiac and uterine drugs of Indian Pharmacopoeia*—Dr. R. N. Ghosh, Calcutta.

Extracts of three herbs, *Saraca Indica*, *Terminalia arjuna* and *Trianthema monogyna* were obtained in various inorganic and organic solvents and tested pharmacologically. Two active principles were detected in *Saraca indica*. One stimulated while the other depressed uterine contractions. The active principles were labile.

An active principle has been detected in *T. arjuna* which stimulated frog's heart. The principle extracted from *Trianthema monogyna* stimulated the uterus of experimental animals.

This scheme has been discontinued with effect from 28th February 1954.

33. *Indian cardiac drugs*—Dr. S. Rangaswami, Waltair.

Both varieties of Indian squill, *Scilla indica* and *Urginea indica* fresh and dried; were examined. Crystalline product were isolated from both varieties; the dried commercial material proved more economical.

34. *Stigmasterol and its isolation*—Dr. R. N. Chakravarti, Calcutta.

Seeds of *Cassia sophera*, *Dolichos lablab*, *D. biflorus*, *Lathyrus sativus*, *Phaseolus mungo* and *Vigna catianga* were examined. Sterols from *C. sophera* and *D. lablab* have been isolated in yields of 0.07 per cent. and 0.1 per cent. respectively. The fractions have been separated into constituent sterols.

35. *Cortisone and corticosterone analogues*—Dr. K. K. Banerjee, Calcutta.

A complete synthesis of 4-keto-7-methoxy 1, 2, 3, 4, 9, 10-hexahydro phenanthrene was achieved with methyl-6 methoxy tetrahexane-2 carboxylate as the starting material. This is a possible intermediate in the preparation of tricyclic analogues of corticosterone.

The scheme has been discontinued with effect from 28th February, 1954.

36. *Preparation of polyvalent vaccine for typhoid, cholera and dysentery*—Dr. S. P. Gupta, Lucknow.

The purpose of this investigation is to prepare a concentrated vaccine by adsorbing on calcium phosphate the specific antigens isolated from *salmonella typhi*, *Vibrio cholerae* and *Shigella dysenteriae*.

*S. typhi*—A protein-free 'depot antigen' absorbed on calcium sulphate has been prepared and found to be non-toxic; it produces antibodies in high titre in rabbits and mice. Antigen extracted by the diethylene glycol method also produced antigens in rabbits.

*Shigella shigae*—An extract prepared with diethylene glycol produced antibodies in rabbits. The molecular size of the antigen has been investigated.

An antigen from *V. cholerae*, which gives protection to mice, has been prepared. The antigen appears to be made up of molecules of a smaller size than that of *S. shigae*.

37. *Study of sulphur analogues of polycyclic hydrocarbons and of sterols for their carcinogenic and cancer inhabiting properties*—Dr. V. R. Khanolkar, Bombay.

Four sulphur analogues of polycyclic hydrocarbons obtained by the replacement of the phenanthrene bridge with a sulphur atom, are being investigated for their carcinogenic properties on experimental animals. Some female mice when painted with one of the compounds (2, 9-dimethyl 2, 3, 5, 6-dibenz-thio-phenanthrene) develop ex papillomes and cystic ulceration.

Histological work to confirm the carcinogenic nature of the compound is being undertaken.

In addition the following new schemes have also been sanctioned by the C. S. I. R.

1. Studies on the Production of Antibiotic substances by *Streptomyces* by Dr. P. N. Nandi, Calcutta.
2. Chemical Investigation of Indian Medicinal Plants with special reference to *Rauwolfia* species and their pharmacology by Dr. Asima Chatterjee, University College of Science, Calcutta.

#### CENTRAL DRUG RESEARCH INSTITUTE, LUCKNOW.

The Central Drug Research Institute is one of the chains of national research laboratories under the Council of Scientific and Industrial Research and was formally opened in February, 1951.

The Institute's functions are :

1. Promotion of drug research in general;
2. Testing and standardization of drugs according to approved methods; and giving expert opinion thereon as a guide for further research developments and production;
3. To offer facilities and help to scientists, universities, special institutions, industries, and others who may not be in a position to carry out investigations;
4. Provision of controlled clinical trials in hospitals, clinics, etc.;
5. Dissemination of scientific knowledge relating to drugs and pharmaceuticals by means of pamphlets, journals etc.;
6. Training of personnel in drug research for which adequate provision does not exist at present in universities and medical institutions.

During the Institute's three years of existence much planning and organizational work has been done and several ambitious programmes have been taken in hand. Suitable scientific personnel have been recruited and modern equipment has been ordered from

foreign countries. The Institute has now six main divisions: (1) Botany and pharmacognosy; (2) Medicinal chemistry; (3) Biochemistry and biophysics including immunochemistry; (4) Pharmacology and chemotherapy; (5) Microbiology and parasitology and (6) Experimental medicine.

In addition, several sub-divisions, such as antibiotics research, virus research, electrotherapeutics research, endocrinological research, histopathological research, etc., have been constituted and these units are likely to develop ultimately into independent divisions. Ancillary services such as a good reference library, a drawing and photomicrographical set-up and a laboratory repair and fabrication service including a glass-blowing unit, have been arranged.

For biological work with laboratory animals of known breed and nutritional and genetic status, a new animal house, costing nearly Rs. 3 lakhs, has been built. This is the first animal house of its kind in India. The nucleus of an "Intelligence and Statistical Section" is already functioning and is attending to inquiries on drugs, drug production and distribution, etc., which are being constantly referred to the Institute in increasing numbers.

The following represents the skeleton programme of the kind of work which each Division is expected to follow. There is bound to be a certain amount of blending of work of each Division with that of other Division since close co-ordination of work done in different Divisions is most essential for any effective programme of research work.

(i) *Division of Botany and Pharmacognosy :*

- (a) Evaluation and standardization of crude drugs with special reference to their identity, quality and purity.
- (b) Researches on 'substitutes' of pharmacopoeial and pharmaceutical codex drugs for inclusion in the proposed Indian Pharmacopoeia.
- (c) Researches on the preservation and storage of crude drugs, including factors leading to deterioration of active principles, fungal infections, etc.
- (d) Improvement in the quality of crude drugs by experimental studies on their cultivation and propagation through the application of genetical and physiological methods.
- (e) Ledgering of information and medicinal plants of special significance to India and publication of Bulletins.
- (f) Assistance to trade by the analysis of crude drugs.
- (g) Cultivation of medicinal plants under natural conditions, and maintenance of a medicinal plant herbarium.

This Division is trying to systematize knowledge of nearly 2,000 indigenous vegetable drugs reputed to be of preventive or curative value in Indian Materia Medica. Considerable confusion exists with regard to their identity and purity and this necessitates the employment of modern methods of systematic botany and plant pharmacognosy to clarify various diverging view points.

Work has been started in the building up of a "herbarium" of crude drugs of India and already about 700 sheets have been prepared. A survey of poisonous plants, which might provide useful therapeutic agents, has been undertaken and a small monograph on "Poisonous Seeds of India" has been compiled. Two monographs on the pharmacognosy of nearly 200 roots, rhizome and leaf drugs of India have been compiled and this has already been published.

An Indian Pharmaceutical Codex has recently been prepared. This book will be useful for both the physician and pharmacist and will help in encouraging the use of indigenous drugs and substitutes for pharmacopoeial drugs which are extensively available in India, thereby reducing the present high cost of medical care in the country.

(ii) *Division of Medicinal Chemistry;*

- (a) Plant Chemistry (indigenous drugs).
- (b) Pharmaceutical Chemistry (Pharmacy).
- (c) Synthetic Chemistry.
- (d) Medicinal Chemicals, and 'substitute' materials.
- (e) Analytical Chemistry, including microchemical analysis.
- (f) Physical Chemistry (Spectroscopy, etc.).

Work under the Division of Medicinal Chemistry has been started on a number of Indian indigenous medicinal plants reputed to be of value in the Ayurvedic, Unani and Tibbi systems of medicine. It is believed that out of the large number of drugs which have been claimed as "Cures" there may be some at least which will justify this claim. The active principles of these medicinal plants are being separated and isolated in pure form and their chemical constitution studied. At present chemical compounds from Varuna, Vakeri, Gindaru, Gugguldhu, Nirvishi, Jonkhamari, Latjir, etc. have been taken up for chemical study by a group of well-trained plant chemists. As soon as pure principles or their derivatives from these plants are available, they will be passed on to the Division of Pharmacology or Microbiology for screening tests against various kinds of disease organisms and for their toxicity, etc.

Side by side with the study of indigenous drugs, work is also in progress along the modern lines of synthetic chemistry to prepare compounds from simpler materials for testing against leprosy, tuberculosis, amoebic dysentery, etc.

(iii) *Division of Biochemistry and Biophysics.*

- (a) The biochemistry of animal and plant tissues, including the study of vitamins, hormones, enzymes, etc.
- (b) The chemical actions and immunity mechanisms of micro-organisms, including viruses and their enzymic systems.
- (c) The study of the chemical actions of antibiotics and other substances on organic tissues and their constituents.
- (d) Radio active tracer methods with phosphorus, Sulphur, iron and carbon to solve biological problems.

(iv) *Division of Microbiology and Parasitology.*

- (a) The culture, natural history and classification of bacteria, viruses, protozoa and other infective and parasitic agents.
- (b) The study of infections and other biological processes, including immunological and pathological reactions, in animals caused by micro-organisms and other infective agents.
- (c) The in vivo and in vitro study of the biological action of chemical agents on micro-organisms and other parasitic agents.
- (d) Host-tissue metabolism and host-parasite relationships with special reference to hormonal disturbances, etc.

Studies in the introduction of Penicillin-resistant organisms, acceleration of the growth of mycobacterium tuberculosis in symbiosis with various fungi, culture and experimental amoebiasis and routine screening tests of growth products of other soil micro-organisms are in progress in this Division.

A number of cases of tropical pulmonary eosinophilia has been examined in collaboration with the King George Medical College, Lucknow. Arsenic therapy, routine haemagglutination tests, animal infectivity tests with serum and sputum, etc. have been continued.

(v) *Division of Pharmacology and Chemotherapy :*

- (a) The action of drugs and other chemical substances on the animal body and its organs.
- (b) The assay of therapeutic agents in animals.
- (c) The absorption, distribution, excretion and detoxication of drugs or other chemical agents in animals.
- (d) Antiseptics, disinfectants, fungicides, insecticides, vermicides, rodenticides, and other chemotherapeutic agents.
- (e) The toxicological effects of drugs and other chemical agents in animals and the quantitative relation of these to their therapeutic effects.

A number of organic chemical compounds have already been prepared and some of these are now under test in the division of pharmacology. The results obtained by biological testing will determine further modification that may be required in the building up of more effective medicinal materials. Among those lines of investigation which have led to steady progress in recent years and which may be expected to continue to lead to valuable discoveries in future, the work on antibiotics stands out. In this Division, enzyme inhibition studies and the elucidation of the mode of action of antibiotics are in progress. The action of penicillin, Dihydrostreptomycin, Aureomycin and Chloromycetin has been studied on plant, fungal, animal and bacterial diastatic enzymes. Extensive screening studies of soil micro-organism of the Gomti river valley have also been taken up. This work is expected to lead to further elucidation of the mode of drug action and might lead to reorientation of ideas and views on the nature of antibiotic action and possibly

to elaboration of newer anti-biotics having stronger properties and feebler toxic actions. In this Division, acute and chronic experiments with living animals or with living tissues of animals have been organized.

Work on blood pressure, respiration, gastro-intestinal movements, kidney and spleen volumes, etc., of animals is being continued. Several new drugs prepared in the Division of Medicinal Chemistry have been tried and some of them have shown some effect in blocking neuromuscular conduction. Preliminary investigations on the alkaloids, hayatin, isolated from *Cissampelos pareira* has also shown some curari-form activity.

(vi) *Division of Experimental Medicine.*

- (a) Determination of therapeutic efficacy by tests on ambulatory patients and later by tests on hospitalised patients.
- (b) Arranging and fuinding therapeutic trials in hospitals.
- (c) Study of dispensing of new remedies.
- (d) Clinical trials of indigenous drugs.
- (e) Pathological, haematological and other aspects of medical therapeutics and toxi-cological studies.

In this Division studies on basal metabolism, cardiovascular, haemodynamics, hypertension, renal electrolyte balance and electro-therapeutics have been started. An interesting problem in connection with depigmentation of the skin in leucoderma has been taken up for study. In collaboration with the endocrinological unit, a pituitary hormone (provisionally named "Pitmelanin") has been isolated, and is being experimented with in bringing about pigmentation of the depigmented skin patches.

In collaboration with Lucknow Medical College, ambulatory patients are brought over to the Research Institute and detailed examination of the blood and body fluids is being conducted to note the serum potassium and sodium concentrations. These findings are expected to help in better elucidation of the mechanism of oedema dropsy and high blood pressure states.

## APPENDIX NO. 12-B

### NOTES ON RESEARCHES CARRIED OUT UNDER THE AUSPICES OF THE INDIAN COUNCIL OF MEDICAL RESEARCH

The Indian Council of Medical Research, formerly the Indian Research Fund Association, has been financing since 1926, researches in indigenous drugs, and the pioneering work of Sir Ram Nath Chopra in this field is well known. A summary of the work done was published in 1939 in a special booklet entitled, "Indigenous Drugs Inquiry—A review of the work by Lieut.-Colonel R. N. Chopra". The work in indigenous drugs is still being financed by the Council at different centres, and the results obtained to date will be published shortly in a memoir which is under preparation. A comprehensive review on 'indigenous drugs research' was also presented by Dr. Mukerji, Director, Central Drugs Research Institute, Lucknow, at the meeting of the Scientific Advisory Board of the Council held in Gwalior in November, 1953. No attempt will, therefore, be made in this note to refer to the work done on indigenous drugs in view of the information already available in the documents referred to above.

It is only during recent years, however, that the Council has sponsored, in some measure, researches in new chemotherapeuticals. Attention was directed, in the first instance, to testing the efficacy of compounds synthesised abroad against infections peculiar to this country and also to the evolution of newer ones. Most of the work done was mainly through grants of fellowships to deserving candidates working in specialised university departments and a few research institutes, and not through the institution of a long term programme at any particular research centre. It is proposed to summarise the work done in this field under the following heads:

- (i) Sulphonamides and sulphones.
- (ii) Palaricides.
- (iii) Antitubercular compounds.
- (iv) Anti-folic acid compounds.
- (v) Antimalarials.
- (vi) Studies in penicillin.

(i) *Studies in sulphonamides and sulphones.*—In early forties, sulphonamides had established themselves as patent antibacterial agents and had stimulated world wide interest in this class of chemical compounds. In order to see the usefulness of sulphonamides in the treatment of plague, an enquiry was started at the Haffkine Institute, Bombay, in 1941. Thirty-five new sulphonamides were synthesised and out of six tested, sulphathiazole, sulphapyridine and sulphadiazine gave significant reduction in case of mortality of plague. Further extension of this work led to the synthesis of methylethyl- and isopropyl-sulphathiazole by Ganapathi which showed suppressive antimalarial activity against *P. knowlesi* in



monkeys. Similarly formaline sulphanilamide and formaline sulphathiazole were found to be as good an sulphathiazole against simian malaria.

Lipophilic derivatives of sulphanilamide and sulphones having chaulmeogric and hydrocarpic residue were synthesized by Raja gopalan in 1946 with the object that they will be more active against acid fast organisms like leprosy bacillus. However, *in vitro* studies failed to show any activity in these compounds. Forty new substituted sulphones prepared as antimalarials by Ganapathi, failed to show any activity against *P. borghei* in mice and *P. gallinaceum* in chicks.

(ii) *Studies in Filaricides.*—Under Dikshit and Venkataramar during 1948-52, extensive chemical and biological investigations have been undertaken on stibanilic acid and related antimony compounds. Alkyl esters of p-stibonobenzoic acid and stibonic acids derived from diaminodiphenylsulphones were prepared in the first instance. Later work included the preparation of homologues of stibacetin and p-phenitidine antimony tartarate as well as nuclear substituted stibanilic acid derivatives. Some of these compounds have shown good activity when tested *in vitro* against *W. bancrofti* especially 4-dodecanoylamid-2-methoxy-phenyl-stibonic acid. Study of p-aminomethyl-benzenostibonic acid (homo-stibonilic acid) by Venkataraman showed it to be twice as active as ureastibamine and hence a number of its N-acyl derivatives were prepared and found to be active and non-toxic when tested against *W. bancrofti* *in vitro*. Trials against dog filaria by Iyer and Rao at Bombay veterinary College gave less favourable results.

A series of salts of antimony tartrates with p-aminobenzoic acid have been made and their filaricidal activities determined. One of the cyanine dye used for filaria viz., 1-ethyl-3: 6-dimethyl-2-phenyl-4-pyrimido-2-cyanine chloride was made into salts of well-known wetting agents, which were found to have increased oil solubility as well as better activity against microfilaria *in vitro*.

(iii) *Studies in Antitubercular compounds.*—Activity of para-aminosalicylic acid (PAS), led to the investigation of easier method for its synthesis by Venkataraman and associates at Bombay. The disodium salt of azosalicylic acid was prepared because it is reduced into two molecules of PAS in the system. A number of esters, ethers, O-acyl derivatives and azodyes of PAS were also synthesised, as well as certain of its salts with wetting agents. 4-amino-2-hydroxy-1-naphthamida and its methoxy analogue were prepared and tested *in vitro* but the results were not encouraging. A number of sulphones were also investigated by Ganapathi which are potential anti-T.B. compounds.

Some of the quinolyl and acridyl-biguanides prepared by Gupta at Indian Institute of Science, Bangalore were also found to be devoid of anti-tubercular activity.

(iv) *Studies in Antifolic acid compounds.*—Since the discovery of folic acid in 1945, folic acid antagonists have been developed for the treatment of leukemias. In order to discover non-toxic folic acid

antagonists, Roy at University College of Science, Calcutta, synthesized analogues of pteroylglutamic acid by replacing p-amino-benzoyl-1 (+) glutamic acid moiety of folic acid with tuluidines, p-aminomethyl-benzene-sulphonamide, p-amino-salicylyl glutamic acid etc. These compounds were tested for their antifolic acid activity against *S. faecalis* R and were found to be active.

Synthetic compounds analogues to pteroylglutamic acid may also be effective against pernicious anaemia and related anaemias. Pal synthesized analogues of pteroylglutamic acid and pteroic acid by substituting p-aminosalicyloyl-1 (+) glutamic acid and p-amino salicylic acid in place of p-amino-benzoyl-1 (+) glutamic acid and p-aminobenzoic acid respectively in the two molecules. These analogues were found to have some antianaemic activity.

(v) *Studies in Antimalarials*.—After the World War II most of the work on synthetic antimalarials was published and reviewed, out of which, the evolution of proguanil (paludrine) as a potent antimalarial was undoubtedly one of the most significant achievements. Simplicity and novelty of chemical structure of proguanil, offered a rich field for further exploration and work was commenced in this field at the Indian Institute of Science, Bangalore in 1947.

Firstly methods for the synthesis of proguanil and its intermediates viz., p-chlorophenylcyano-guanidine and isopropylamine were investigated and optimum experimental conditions established. Later on a large number of sulphabiguanide derivatives having metachloridine sulphanilamide, sulphathiazole, sulphadiazine, sulphapyrazine sulphamerazine sulphamethazine, 3:5-dibromo sulphanilide or N<sup>1</sup>-benzoyl-phanilamide moiety attached to an aryl-biguanide chain were synthesized. Sulpha-biguanides derived from sulphanilamido-pyrimidines showed some antimalarial activity against experimental malarias but they were unable to compete with antimalarial activity of proguanil.

Several heterocyclic substituted arylbiguanides viz., N<sup>1</sup>-(7/5-chloro-8-quinolyl)-N<sup>5</sup>-aryl-biguanide, N<sup>1</sup>-(2-chloro-7-methoxy-5-acridyl)-N-aryl-biguanides, and N<sup>1</sup>-2-thiazoly-N<sup>2</sup> aryl-biguanides were synthesised but this class was generally devoid of antimalarial activity. N<sup>1</sup>-N<sup>3</sup>-disubstituted guanidines studied similarly were also inactive.

Considering the lack of activity in the above types of biguanides, Bami investigated a series of N<sup>1</sup>-aryl-N<sup>5</sup>-alkyl-biguanides very similar to proguanil. Amongst these, N<sup>1</sup>-bromophenyl-N<sup>5</sup>-isopropyl-biguanide (a bromo analogue of proguanil, termed "Bromoguanide") was found to be most active. It was exhaustively studied by Jaswant Singh and co-workers at the Malaria Institute of India, Delhi, against experimental avian and simian infections and these encouraging results led to its limited clinical trial under Dr. Chaudhury at School of Tropical Medicine Calcutta. This compound compared favourably with proguanil in the treatment of human malarias but failed to establish any advantage over the parent drug.

In quest of prophylactic and curative antimalarials, Ganapathi at Haffkine Institute, Bombay first prepared in 1948 a number of compounds having p-chlorophenylamino group attached to a thiazole ring, which itself carried substituents characterising the well-known antimalarials. Further work included synthesis of several amidines,

quinoline-sulphones, alkyl thiazoles, quinoline-thiazoles, quinoline-guanidines, thioureas, dithiobiurets, biguanides, disubstituted amines and alkyl sulphones which were screened against *P. berghoi* in mice and/or *P. gallinaceum* in mosquitoes (*aedes*) for their antimalarial activity. Some of the biguanides and alkyl-thiazoles, proved to be active, but in rest of the cases the activity was either negligible or absent completely.

Synthetic work on the preparation of well-known antimalarials like proguanil and chloroquin by newer methods, was also successfully undertaken.

(vi) *Studies in Penicillin*.—This study was started in 1946 at the Haffkine Institute, with the object of studying the method of manufacture of penicillin and related problems. Three different extraction methods were tried in order to obtain the optimum conditions for production. The nature of the product(s) obtained, by different strains of *P. chrysogenum* under different conditions was studied and a rapid titrimetric method for the assay of penicillin was also standardised.



सत्यमेव जयते

## APPENDIX NO. 13

LIST OF PRINCIPALS, PROFESSORS OF SURGERY, PHARMACOLOGY ETC. OF VARIOUS MEDICAL COLLEGES AND OFFICIALS OF THE PUBLIC HEALTH DEPARTMENTS OF THE STATE GOVERNMENTS FROM WHOM REPLIES TO THE MEDICAL QUESTIONNAIRE WERE RECEIVED.

### WEST BENGAL:

1. Dr. M. Pin. M.B., F.R.C.S., Principal, Calcutta National Medical Institute, 32 Gorachand Road, Calcutta.

2. *MEDICAL COLLEGE, Calcutta* (Government of West Bengal):

(i) Professor-Director, Dept. of Medicine.

(ii) Professor-Director, Dept. of Midwifery.

(iii) The Professor of Pharmacology.

(iv) The Professor of Hygiene.

(Forwarded thro' The Principal, M.C., Calcutta).

3. Prof. B. N. Gosh, R. G. Kar Medical College, Pharmacological Dept., 1, Belgachia Road, Calcutta.

4. S. K. Sen, Principal, R. G. Kar Medical College, 1, Belgachia Road, Calcutta.

5. D. Mitra, Professor of Hygiene R. G. Kar, Medical College.

6. (Tho' A. K. Dutta Gupte, Principal, Nilrathan Sircar Medical College, Calcutta).

(i) A. Das, Professor of Medicine.

(ii) Professor of Midwifery.

(iii) N. Kovar, M.D., M.R.C.P., Associate Prof. of Medicine.

7. H. Roy, M.D. (Cal.), Hon. Physician, N.R.S. Hospital.

8. Physician In-charge, Podiatric Dept., Nilrathan Sircar Medical College, Calcutta.

9. Senior Visiting Physician, Skin Dept., N. S. Medical College Hospitals, Calcutta.

10. D. M. Gupta, Teacher of Medicine and Visiting Physician, M.S.M. School and Hospitals, Calcutta.

11. Dharmandra, Leprosy Research Dept., School of Tropical Medicine, Calcutta.

12. Nalini Ranjan Sen Gupta, 91, Chowringhee Road Cal. 20.

13. P. K. Sen, Physician, Chest Dept., Medical College Hosp. Cal.

**ORISSA:**

- (1) Principal, Sriram Chandra Bhanj Medical College, Cuttack.
- (2) B. N. Sahu, Prof. of Medicine, Bhanj Medical College, Cuttack.
- (3) J. Dei, Professor of Midwifery, Bhanj Medical College, Cuttack.
- (4) R. N. Misra, Prof. of Surgery, Bhanj Medical College, Cuttack.
- (5) K. N. Ojha, Prof. of Pharmacology, Bhanj Medical College, Cuttack.
- (6) R. G. Panigrahi, Reader in Hygiene, Bhanj Medical College, Cuttack.

**BIHAR:**

1. (Thro' B. N. Banerji, B.Sc., M.B., F.R.C.S., Principal, Darbhanga Medical College, Laherisara):

- (i) Dr. M. Prasad, Professor of Pathology.
  - (ii) Dr. Y. K. Sinha, Dept. of Pharmacology and Therapeutics.
  - (iii) S. R. Verma, Acting Professor of Medicine.
2. D. Renu, Principal, Patna Medical College.

**NAGPUR:**

(Thro' Dean, Medical College and Hospital, Nagpur):

- (i) K. N. Sinha, Prof. of Pharmacology.
- (ii) Prof. of Medicine.
- (iii) Prof. of Surgery.
- (iv) Prof. of Midwifery and Gynaecology.
- (v) Reader of Hygiene and Public Health.
- (vi) Dean.

**UTTAR PRADESH:**

1. Dr. R. B. Singhal, M.B.B.S., Kashipur (Nainital).
2. (Thro' V. S. Mangalik, M.D., D.C.P. (Lond.), Dean, Faculty of Medicine, Lucknow University).
  - (i) Prof. of Clinical Medicine, K. G. Medical College.
  - (ii) D. Kutty, Offg. Prof. of Obstetrics and Gynaecology K. G. Medical College.
  - (iii) M. L. Gujral, Head of Dept. of Pharmacology, K. G. Medical College.

**VINDHYA PRADESH:**

1. Civil Assistant Surgeon, I/C District Hospitals, Datia-V.P.
2. Civil Assistant Surgeon, I/C Tikamgarh District Hospitals.

3. (Thro' Director, Medical and Health Services, Bhopal):
  - (i) Civil Asst. Surgeon, I/C Dist. Hosp. Satna, V.P.
  - (ii) Supdt. Sultana Zanana Hospital, Bhopal.
  - (iii) Health Officer, Municipal Board, Bhopal.
  - (iv) Civil Surgeon and Supdt. Hamidia Hospital, Bhopal.

#### REWA:

1. Civil Asst. Surgeon (Grade I) I/C Dist. Hospital, Umaria.
2. Supdt. Gandhi Memorial Hospital, Rewa, V.P.

#### BILASPUR:

1. (Thro' W. C. Malhotra, Chief Medical Officer, Bilaspur Simla Hills), Bilaspur:
  - (i) Asst. Surgeon.
  - (ii) Asst. Surgeon, Primary Health Centre, Jukhala.

#### KUTCH-BHUJ:

1. Chief Medical Officer, Kutch-Bhuj.

#### MYSORE STATE:

- (Thro' S. Vasudeva Rao, Principal, Medical School, Bangalore):
- (i) C. V. Shankarambal, F.R.C.S. Surgeon Victoria Hospital and Lecturer in Surgery, Medical School, Bangalore.
  - (ii) Dr. Mirle Puttiah, B.Sc., M.B.B.S. Lecturer in Pharmacology, Medical School, and Physician, Victoria Hospital, Bangalore.
  - (iii) Dr. Pankajam Maduram, Asst. Surgeon, CI. I, Vani Vilas Hospital, Bangalore and Lecturer in Midwifery, Medical School, Bangalore.
2. Jt. reply from Dr. Sivaram, M. R. Mahadevan and B. K. Narayana Rao, the City Dispensary and Laboratory, Balepet, Bangalore City.
  3. Dr. Mirle Puttaiya, Kanthiniwas, Basavangudi, Bangalore.
  4. Principal I/C, Medical College, Mysore.

#### MADRAS:

(Thro' Syed Abdus Subhan, Secretary to Government Health Dept.) and Dr. M. V. Ramanamurthi, M.B.B.S., F.R.C.S. (Edin.), Director of Medical Services, Madras.

- (i) Dr. K. S. Viswanathan, M.P. (Harvard), Director of Public Health, Madras.
- (ii) S. N. Gantayet, Supdt., K. G. Hospital, Visakhapatnam, Maharanipets.
- (iii) Dr. Mohd. Ismail, Dist. Medical Officer, Madurai, Tallakulam P.O., P.B. No. 3.

- (iv) Dr. G. Thimma Reddi, D.M.O., Krishna, Machilipatnam.
- (v) Supdt., Government Hospital for women and children, Egmore, Madras.
- (vi) Dr. B. Govindaraj Shanai, D.M.O., P. Box No. 8, Tanjore.
- (vii) District Medical Officer, Nellore.
- (viii) Dr. P. R. Kalyanasaudaram, D.M.O., Salem.
- (ix) Medical Officer, Government Hosp. Tiruchengode, Salem Dt.
- (x) Civil Asst. Surgeon, Government Hosp. Mettur Dam.
- (xi) Civil Asst. Surgeon, Government Hosp. Krishnagiri.
- (xii) Resident Medical Officer, Government Children's Leprosy Sanatorium, Ethapur.
- (xiii) Dr. S. Balasubramaniam, D.M.O., Coimbatore.
- (xiv) Dr. K. N. Rao, M.D. F.R.C.P., F.I.C.S., Supdt. Government T. B. Sanatorium Tambaram.
- (xv) Dr. C. R. Prasad Rao, M.D., Dean, Government Gen. Hosp. Madras.
- (xvi) Dr. K. S. Sanjivi, Prof. of medicine, Madras Medical College.
- (xvii) Dr. R. Subramaniam, Add. Prof. of Medicine, Madras Medical College.
- (xviii) Dr. M. G. Prabhu, Prof. of Therapeutic Madras Medical College.
- (xix) Dr. N. Narayan Prabhu, E.N.T. Surgeon, Govt. Gen. Hosp.
- (xx) Dr. K. P. G. Menon, Hon. Physician, Govt. Gen. Hosp. Madras.
- (xxi) Dr. R. S. Kesavaraj, D.M.O., Guntur.
- (xxii) Dr. Imaduddin, M.O. I/C, Govt. Hosp. Tenali.
- (xxiii) Civil Asst. Surgeon, Govt. Hosp. Ongole.
- (xxiv) M.O. Govt. Hosp. Narasaraopet.
- (xxv) Civil Asst. Surgeon, Govt., Hosp. Bapatla.
- (xxvi) Dr. A. N. Subaraman, D.M.O., Trichirapally.
- (xxvii) Director of Public Health, Madras, Qilpauk.

#### ASSAM:

1. Chief Medical Officer, Manipur, P.O. Imphal.

#### TRAVANCORE AND COCHIN:

(Thro' The Surgeon General, Trivandrum).

1. Supdt. Women and Children's Hosp. Trivandrum (S. Joseph).
2. Supdt. the Sri A. T. Hospital, Ulloor, Trivandrum.
3. District Medical Officer, Trivandrum.
4. Dr. A. K. Menon, General Hosp. Physician, Ernakulam.

**ANDAMAN AND NICOBAR ISLANDS:**

1. Dr. P. R. Sondhi, F.R.C.S., Senior Medical Officer, Port Blair.

**JAMMU AND KASHMIR:**

(Thro' S. M. Hassan, Dy. Director of Health Services, (Jammu and Kashmir Government).

1. Chief Medical Officer, Srinagar—Kashmir.
2. Supdt. SMHS Hospital, Srinagar.
3. Chief Medical Officer, Jammu.

**BIHAR:**

(Thro' S. M. Hassan, Dy. Director of Health Services (Medi.) Bihar.

1. Dr. H. Prasad, Supdt. Patna Medical College Hosp. Patna.
2. S. B. Lal, Asst. Director of Public Health (Nutrition) Bihar.
3. N. L. Mukherjee, Officer i/c, National Malaria Control Programme, Bihar.
4. P. N. Singh, Supdt. Darbhanga Medical College Hospital.
5. Dr. K. K. Sinha, M.O., T. B. Centre, Patna.
6. Dr. S. P. Jha, Director T. B. Centre, Patna.
7. Dr. Achari, Ph. D., M.B.B.S., Director, Bihar Drugs Control Lab. Patna.

**PUNJAB:**

1. The Director of Health Services, Punjab.

**HYDERABAD STATE:**

1. M. K. Pandit, Principal, Medical College and Officer I/C, Osmania Hospital, Hyderabad Dn.

**RAJASTHAN:**

1. Kesho Ram Gupta, L.A.M.S., Gokal Bazar, Rewari.

**ASSAM:**

(Thro' Dr. H. C. Barua, Principal, Assam Medical College, Dibrugarh).

1. K. N. Kashyap, Asst. Prof. of Surgery, A.M.C., Dibrugarh.
2. Dr. P. N. Barua, Prof. of Clinical and Operative Surgery.
3. Dr. R. Labhaya, Prof. of Ophthalmology, Dibrugarh.
4. Dept., of Obstetrics and Gynaecology Dibrugarh.
5. Prof. of Cl. Medicine, Dibrugarh.

**MADHYA BHARAT:**

1. Principal, M.G.M. Medical College, Indore.
2. B. Shai, M.D., Principal, G. R. Medical College Gwalior.

**WEST BENGAL:**

1. Special Officer (Supervision) Directorate of Health Services.



**TRAVANCORE-COCHIN:**

(Thro' Principal, Medical College, Trivandrum 4).

1. Prof. of Surgery. 2. Prof. of Pharmacology. 3. Prof. of Medicine.
4. Prof. of Preventive Medicine.

**MADHYA BHARAT:**

Director of Health Services, Madhya Bharat, Gwalior.

**RAJASTHAN:**

1. Professor of Surgery and Principal, Sawai Mansingh Medical College, Jaipur.

2. Dr. R. B. Arora, Professor of Pharmacology, Sawai Mansingh Medical College, Jaipur.

3. Dr. H. L. Chopra, Head of the Department of Hygiene and Deputy Director of Medical and Health Services, Jaipur.

4. Dr. R. M. Kasliwal, Professor of Medicine, S.M.S. Medical College, Jaipur.

**ORISSA:**

(Through Director of Health and Inspector General of Prisons).

1. Professor of Ophthalmology, S.C.B. Medical College, Cuttack.

2. Dr. R. N. Sahu, Professor of Medicine Medical College, Cuttack.

3. Dr. J. Dei, Professor of Obstetrics Medical College, Cuttack.

4. Sr. Sarat Chandra, Member, Indian Medical Association, Orissa Provincial Branch, Cuttack.

5. Dr. M. K. Mukherjee, General Pharmacy, Mangalabag, Cuttack.

6. Dr. G. S. Mahapatra, Assistant Professor of Medicine, S.C.B., Medical College, Cuttack.

7. Dr. K. N. Ojha.

8. Hon. Secretary, I.M.A., Cuttack Branch.

**BOMBAY STATE:**

(Through Principal, B. J. Medical College Ahmedabad).

1. R. D. Vohra, Medical Officer of Health, Municipal Corporation Ahmedabad.

2. Professor of Pharmacology, B. J. Medical College, Ahmedabad.

3. Hon. Obstetricians and Gynaecologist, Civil Hospital and B.J. Medical College, Ahmedabad.

4. Hon. Surgeons, Civil Hospital and B. J. Medical College, Ahmedabad.

(Through Principal, B. J. Medical College, Poona).

1. N. T. Advani, *Ex-Officio* Lecturer in Preventive Medicine.

2. Dr. (Smt.) R. Aiman, Professor of Pharmacology.
3. Dr. (Smt.) S. Tilak, Hon. Obstetrician and Gynaecologist.
4. Dr. K. Y. Rege, Hon. Surgeon.
5. Dr. P. L. Deshmukh, Hon. Physician.
6. Dr. K. B. Grant, Hon. Physician.
7. Dean, Topiwala National Medical College, Bombay 8.  
(Through Principal, Grant Medical College, Bombay).
1. Professor of Pharmacology.
2. Hon. Lecturer in Preventive Medicine (V. V. Puri).  
(Through Principal Medical College, Baroda).
1. P. M. Kuhar, Hon. Physician, Shree Sayaji General Hospital.

#### PUNJAB:

(Through Principal, Christian Medical College, Ludhiana).

1. Consolidated reply of doctors of the above college.  
(Through Principal, Medical College, Amritsar).
1. Department of Medicine.
2. Ram Chand Khanna, Department of Surgery.
3. Pharmacology Department.
4. S. R. Dhall, Department of Midwifery.
5. Hygiene Department.
6. Principal, Arya Medical School, Ludhiana.

#### HIMACHAL PRADESH:

(Through Director of Health Services, Medical Department H. P. Government, Simla).

1. D.M.O. Mahasu.
2. D.M.O. Mandi.
3. D.M.O. Sirmur.
4. D.M.O. Chamba.
5. Civil Surgeon, (D.M.O.) Mahasu and Simla

#### MYSORE STATE:

(Through B. R. Ramalinga Reddy, Director of Medical Services in Mysore).

1. P. Krishna Rao, Supdt. Victoria Hospital Bangalore.
2. Supdt. Minto Ophthalmic Hospital Bangalore.
3. V. R. Naidu, Supdt. Krishnarajendra Hospital Mysore.
4. S. Narayana Setty, M.O., P. K. Sanatorium, Mysore.
5. Supdt. Cheluvanba Hospital Mysore.
6. T. Chandrasekharaiya, Director of Public Health in Mysore.

#### MADRAS:

(Through The Principal, Andhra Medical College, Visakhapatnam).

1. Christian Medical College, Vellore.
2. Madras Medical College, Madras.

3. Stanley Medical College and Hospital Madras.
4. Dr. S. Srinivasan, Medical Practitioner, Tiruvarur.

#### MADHYA PRADESH:

(Through Director of Health Services, Medical Section, M.P.).

1. Director of Health Services, Medical Section.
2. Civil Surgeon, Jabalpur.
3. Civil Surgeon, Akola.
4. Civil Surgeon, Bhandara.
5. Dean, Medical College and Hospital, Nagpur.
6. Civil Surgeon, Buldana.
7. Civil Surgeon, Betul.
8. Civil Surgeon, Nagpur.
9. Civil Surgeon, Raipur.
10. Civil Surgeon, Wardha.

#### PEPSU:

(Through Director of Health and Medical Services, Patiala).

1. Dr. Ram Singh, X-Ray Institute.
2. Dr. Amarjit Singh, Special Officer, Drugs and stores.
3. Dr. N. P. Jain, Bhupindra Clinical Laboratory.
4. Dr. Jagdish Singh, Supdt., Rajindra Hospital.
5. Ophthalmic Surgeon, Ranindra Hospital.
6. Deputy Director, Public Health, Patiala.

#### BOMBAY:

(Through Surgeon General, Bombay).

1. K. R. Patil, Civil Surgeon, Baroda.
2. Civil Surgeon, Ahmedabad.
3. Civil Surgeon, Belgaum.
4. Civil Surgeon, Poona.
5. Supdt. J. J. Group of Hospitals, Bombay.
6. Director of Public Health, Poona.

#### *Medical Associations.*

- Indian Medical Association.  
All-India Medical Licentiates Association.

## APPENDIX NO. 14.

### LIST OF MINIMUM EQUIPMENT FOR THE EFFICIENT RUNNING OF A PHARMACY.

I. *Name*.—A pharmacy shall bear a name recognised by the licensing authority.

II. *Entrance*.—The front of a pharmacy shall bear an inscription "Pharmacy". A night bell shall be placed at the side of the door and the entrance to a pharmacy providing night service shall be lit during hours of darkness.

III. *Premises*.—The premises of a pharmacy shall be separated from rooms for private use. The premises shall be well-built, dry, well-lit and ventilated and of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in a cleanly visible and appropriate manner. In general the area of a room shall not be less than 64 sq. ft. for each person working therein. The height of the premises shall be at least 8 ft.

The floor of the pharmacy shall be smooth and washable. The walls shall be plastered or tiled or oil painted so as to maintain a smooth, durable and washable surface devoid of holes, cracks and crevices.

A pharmacy shall be provided with ample supply of good quality water. (The water shall be either filtered through a filter or must be freshly boiled and cooled).

The dispensing department shall be separated by a barrier to prevent the admission of the public.

IV. *Furniture and Apparatus*.—The furniture and apparatus of a pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment.

Drugs, Chemicals and medicaments shall be kept in a room appropriate to their properties and in such special containers as will prevent any deterioration of their contents or of the contents of containers kept near them.

Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust.

Every container shall bear a label of appropriate size, easily readable, with names of medicaments as given in the Pharmacopoeias.

A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with washable and impervious material like stainless steel, laminated plastics, etc.

A pharmacy shall be provided with a cupboard with lock and key for the storage of poisons and shall be clearly marked with the word "poison" in red letters on a white background.

Containers of all concentrated solutions shall bear a special label or marked with the words "To be diluted" in the white letters on a black background.

A pharmacy shall be provided with the following minimum apparatus and books necessary for making of official preparations and prescriptions:—

*Apparatus:*

- Balance, dispensing, sensitivity 2 mg.
- Balance, counter, capacity 7 lbs. sensitivity 15 grains.
- Bath, water, copper 6".
- Beakers, lipped, Pyrex, assorted sizes, 50 to 1000 ml.
- Bottles with droppers, amber or other colour, assorted sizes.
- Bottles, prescription, graduated, assorted sizes.
- Bottles, prescription, ungraduated, assorted sizes.
- Corks, assorted sizes and tapers.
- Cork extractor.
- Cork presser.
- Evaporating dishes, porcelain 6", 3".
- Filter paper.
- Flasks, Erlenmeyer, Pyrex, assorted sizes.
- Funnels, long-stem, 60 angle, 3".
- Funnels, plain, 6", 4", 3".
- Funnels, straining.
- Gauze cloth.
- Infusion pot.
- Litmus paper, blue and red.
- Measure glasses, 2 drachm, 1 oz., 2 oz., 10 oz., 20 oz.
- Measure glasses, cylindrical, assorted sizes 10 to 500 ml.
- Mortars and pestles, glass, assorted sizes (6", 4", 2").
- Mortars and pestles, wedgwood, assorted sizes (12", 8", 4").
- Ointment pots with bakelite or suitable durable caps, assorted sizes.
- Ointment slab, porcelain, 12", 9".
- Pill finisher, boxwood.
- Pill Machine.
- Pill boxes, assorted sizes.
- Pipettes, graduated, 10 ml., 2 ml., 1 ml.
- Powder folder.
- Rack, test-tube.
- Ring stand (retort) iron, complete with rings.
- Rubber stamps and pad.
- Rubber stoppers, assorted sizes.

Scissors.

Shops Rounds.

Spatulas, rubber or vulcanite, assorted sizes.

Spatulas, stainless steel, assorted sizes.

Spirit lamp.

Stirring rods, glass, assorted lengths and diameter

Suppository mould.

Test tubes, Pyrex.

Thermometer, 0 to 200°C or 0 to 350°F.

Tripod stand.

Watch glasses 6", 4", 3",

Weights, avoirdupois 1/2 oz. to 7 lbs.

Weights, Metric 1 mg., to 100 gm.

Weights, apothecaries 1/2 gr. to 2 drachms.

Wire Gauze, Asbestos centre 5"×5".

#### *Books:*

The British Pharmacopoeia (Current Edition) and Addenda.

The British Pharmaceutical Codex (Current Edition) and Addenda.

The Indian Pharmacopoeial List, 1946.

The Extra Pharmacopoeia (Martindale), Vols. I and II.

The Dangerous Drugs Act, 1930.

The Drugs Act, 1940.

The Drugs Rules, 1945.

The Pharmacy Act, 1948.

Other Acts and Rules affecting the business of a pharmacist.

*V. General provisions.*—A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises.

The pharmacist in charge shall always put on clean white overalls.

The premises and fittings of the pharmacy shall be properly kept and everything must be in good order and clean.

All records and registers shall be maintained in accordance with the laws in force.

Any container taken from the poison cupboard shall be replaced therein immediately after use and the cupboard locked. The keys of the poison cupboard shall be kept in a safe place.

Medicaments when supplied shall have labels conforming to the provisions of the laws in force.

## BIBLIOGRAPHY

### GOVERNMENT PUBLICATIONS—

- 1 BOMBAY GOVERNMENT . Report of the Haffkine Institute, 1951.
- 2 BOMBAY GOVERNMENT . Report of the Committee for the Improvement of Slaughter Houses in the State of Bombay, 1953.
3. INDIA GOVERNMENT . Report of the Panel on Fine Chemicals Drug and Pharmaceuticals, 1944-45.
- 4 INDIA GOVERNMENT . . Drug Standard Control—The Drugs Act 1940 and the Drugs Rules, 1945 thereunder
- 5 INDIA GOVERNMENT . Report of the Drug Enquiry Committee 1930-31.
- 6 INDIA GOVERNMENT . Report of the Indian Tariff Board on Chloroform, Potassium Permanganate, Ether Sulphuric and Anaesthetic Industries, 1947.
- 7 INDIA GOVERNMENT . Report of the Committee on Indigenous Systems of Medicine, 1948.
- 8 INDIA GOVERNMENT . Factories Act, 1948 (Act LXIII of 1948).
- 9 INDIA GOVERNMENT . The Pharmacy Act, 1948.
- 10 INDIA GOVERNMENT . Report of the Indian Tariff Board on the Liver Extract Industry, 1950.
- 11 INDIA GOVERNMENT . Report of the Expert Committee (Excise) 1951.
- 12 INDIA GOVERNMENT . Import/Trade Policy for the licensing periods January 1951 to June 1954.
13. INDIA GOVERNMENT . The Industries (Development and Regulation) Act, 1951.
- 14 INDIA GOVERNMENT . Report of the Panel for Pharmaceutical Industry, 1951.
- 15 INDIA GOVERNMENT . The First Five Year Plan, 1951—56.
- 16 INDIA GOVERNMENT . Census of India, 1951 Vol. I, Part 1-A—Report.
- 17 INDIA GOVERNMENT . Patent Office Handbook (8th Edition), 1951—Indian Patents and Designs Act, 1911.
- 18 INDIA GOVERNMENT . Report of the Indian Tariff Board on the reduction of import duty on Meta-amino phenol used in the manufacture of para-amino Salicylic acid, 1952.
- 19 INDIA GOVERNMENT . Programmes of Industrial Development (1951—56) published by the Planning Commission, 1953.
- 20 INDIA GOVERNMENT . Report of the Special Cinchona Committee, 1953.
- 21 INDIA GOVERNMENT . Report of the Ministry of Commerce and Industry for the year 1953-54.

## TREATISES.

1. CHOPRA R. N. BT.-COL. Indigenous Drugs Enquiry—A review of the work (July 1939).
2. CHOPRA R. N. BT.-COL. Indigenous Drugs of India.
3. COUNCIL OF PHARMACEUTICAL SOCIETY OF GT. BRITAIN—Antibiotics.
4. COUNCIL OF PHARMACEUTICAL SOCIETY OF GT. BRITAIN—Hormones—a Survey of their properties and uses.
5. DREW, JOHN DR. MAN, Microbe and Malady 1940.
6. INDIAN COUNCIL OF MEDICAL RESEARCH—A review of researches carried out under the auspices of the Indian Council of Medical research (Nov. 1953).
7. KIRTIKAR AND BASU, Indian Medicinal Plants.
8. KREMERS, EDWARD AND LINDANG, GEORGE—History of Pharmacy, 1940.
9. NATIONAL WHOLESALE DRUGGISTS ASSOCIATION, NEW YORK—Basis and Development of Fair Trade, 1950.
10. NAYAR S. L. & CHOPRA, I. C. Distribution of British Pharmacopoeial Drug Plants and their substitutes growing in India.
11. P.A.T.A.—P.A.T.A. Year Book—1953.
12. ROBSON, J. M. & KEULE, C. A.—Recent advances in Pharmacology.
13. SMITH, AVSTIN & HARNICK, AARTHOR O.—Drug Research and Development, 1948.
14. WORLD HEALTH ORGANISATION—Fourth Report of the Expert Committee on Insecticides—technical report series 1954.

## GENERAL.

1. British Pharmacopoeia.
2. British Pharmaceutical Codex.
3. Council on Pharmacy and Chemistry of the American Medical Association.
4. Dangerous Drugs Act, 1930.
5. Extra Pharmacopoeia (Martindele) Vols. I and II.
6. Federal Food Drugs and Cosmetic Act of the U.S.A.
7. Food and Drugs Act, Canada.
8. Indian Pharmacopoeial List, 1946.
9. Indian Pharmaceutical Codex.
10. Indian Chemical & Pharmaceutical Industry, 1951—Report from the Indian Chemical Manufacturers' Association.
11. Modern Drug Encyclopedia and Therapeutic Index (5th Edition).
12. Pamphlet entitled "Central Drug Research Institute, Lucknow" by the Council of Scientific and Industrial Research, New Delhi.
13. Reports of the Scientific Advisory Board of the Indian Council of Medical Research for the years 1944-1952.
14. U.S. Pharmacopoeia.



## JOURNALS.

- 1 ADDINALL, C. R. . . . . Synthesis and production of vitamins. *Chemical and Engineering News* (Dec. 1944), Vol. 22, No. 24 pp. 2174—2178 and 2214.
- 2 BANGNALL, H. H. AND STOCK, F. G. . . . . Vitamin A and the Public Analyst. *The Pharmaceutical Journal* (Jan. 1952) pp. 58—59.
- 3 BENGAL IMMUNITY RESEARCH INSTITUTE, CALCUTTA. . . . . Standardisation of Indian Glass Containers. *Immunity Bulletin* (9152) pp. 5—8.
- 4 BENGAL IMMUNITY RESEARCH INSTITUTE, CALCUTTA. . . . . Problem of Cork in India *Immunity Bulletin* (1952) p. 62.
- 5 BERRY, H. . . . . A review of disinfectants and disinfection. *The Pharmaceutical Journal* (Sept. 1951) pp. 183—187.
- 6 BOHMFALK, JOHN, F. . . . . Research-Blend of efforts *The Modern Pharmaceutical Industry* (No. 4 in a series pp 5186—5191).
- 7 BOYES G. R. . . . . The Pharmacist and Therapeutics. *Journal of Pharmacy and Pharmacology* (Vo.) V., No. 10 pp. 657—671 (Oct. 1953).
- 8 CHAUDHRI R. N. & DUTTA, B. N. . . . . Chemotherapy of Malaria with special reference to the work done in India. *Indian Medical Gazette* (Jan. 1953) Vol. LXXXVIII No. 1—A review.
- 9 DATTA AND MUKERJEE . . . . . Pharmacognosy of Indian Root and Rhizome Drugs and Pharmacognosy of Indian Leaf Drugs. ....
- 10 DESCRIPTION OF THE PROCESS AT THE ROCHE PRODUCTS LTD., FACTORY AT WELWYN. . . . . The manufacture of Vitamin C on the Industrial scale. *Industrial Chemist* (March 1947) pp. 169—177.
- 11 DIMBLELY V. . . . . Glass for Pharmaceutical purposes. *Journal of Pharmacy and Pharmacology*, Vol. V, No. 12 (Dec. 1953) pp. 969—988.
- 12 ENGELS, W. H. . . . . Development of Chemicals for the Pharmaceutical Industry. *Journal of the American Pharmaceutical Association* (Practical Pharmacy Edition) pp. 164—190.
- 13 EWINS, A. J. . . . . British achievements in Sulphonamide Research and production. *The Pharmaceutical Journal* (April 1951) pp. 312—314.
- 14 FISHBURN, A. G. . . . . British achievements in Pharmaceutical Research. *The Pharmaceutical Journal* (April 1951) pp. 299—300.
- 15 FURBAIRN J. W. . . . . Some recent advances in the knowledge of the constituents of Vegetable drugs. *Journal of Pharmacy and Pharmacology*, Vol. V, No. 5 (May 1953) pp. 281—290.
- 16 GRAY, T. C. . . . . A review of local Anaesthetics. *Journal of Pharmacy and Pharmacology*, Vol. VI, No. 2 (Feb. 1954) pp. 89—110.
- 17 GUTURIE, DOUGLAS . . . . . Simple herbs and Synthetic remedies. *The Pharmaceutical Journal* (Jan. 1952) p. 57.

- 18 HAMPSHIRE C. H. . . . British achievements in The Pharmaceutical literature. *The Pharmaceutical Journal* (April 1951) pp. 301—302.
- 19 HARTLEY F. . . . The nomenclature of drugs. *The Pharmaceutical Journal* (Jan. 1952).
- 20 HARTLEY F. . . . British achievements in Fine Chemical Production. *The Pharmaceutical Journal* (April 1951) pp. 306—307.
- 21 KILLEFFER, D. H. . . . Vitamin Status *Chemical and Engineering News* (Aug. 1940) pp. 670—671
- 22 LINSTAD HUGH N. . . . British achievements in Pharmaceutical organisation. *Pharmaceutical Journal* (April 1951) pp. 308—311.
- 23 LUTHRA, JAI CHAND . . . Some important Economic Plants and their cultivation. *Indian Farming* Vol. XI, No. 1 (Jan. 1950)
- 24 LUTHRA, JAI CHAND AND SURI DURGA DAS. Cultivation of some important Drugs in the Punjab. *Special Bulletin published by the Agriculture Department of the Government of Punjab* (1936).
- 25 MEMBER, PHARMACEUTICAL SOCIETY A Century of Pharmaceutical Chemicals. *Industrial Chemist* (July 1947) pp. 423—429.
- 26 MUKERJEE B. DR. Review on indigenous drugs Research (Present & future) presented before the inaugural meeting of the Indian Council of Medical Research at Gwalior in Nov. 1953. ....
- 27 PECK WILLIAM, C. . . . British achievements in Pharmaceutical Plant design. *The Pharmaceutical Journal* (April 1951) pp. 303—305.
- 28 PRASAD, S. . . . Role of Pharmacognosy in the Development of our Drug Industry. *Chemical Age* (Series 1—April 1950) pp. 135—138.
- 29 RANDOLPH T., MAJOR . . . Industrial Development of Synthetic Vitamins. *Chemical and Engineering News* (April 1942) Vol. 20, No. 8, pp. 517—523.
- 30 REPORT OF A SYMPOSIUM ON CONTAINERS AND CLOSURES. ... *Journal of Pharmacy and Pharmacology* Vol. V, No. 12 (Dec. 1953) pp. 990—1023.
- 31 RIGBY GERALD . . . British achievements in Pharmaceutical Laboratory Apparatus. *The Pharmaceutica Journal* (April 1951) pp. 318—320.
- 32 ROFFEY, F. . . . Lecture on Development of Chemical processes. *Lectures, Monographs and Reports. The Royal Institute of Chemistry* (1949).
- 33 SHERNDAL, ALFRED, E. Chemistry and development of Atabrine and Plasmochin. *Chemical and Engineering News* (July 1953, Vol. 21, No. 14, pp. 1154—1158).
- 34 SINGER, J. H. . . . British achievements in Factory layout and packaging. *The Pharmaceutical Journal* (April 1951) pp. 315—317.
- 35 STAFF REPORT . . . This Antibiotic age *Chemical and Engineering News* (March 1951) pp. 1190—1195.

- 36 ZINSEER, JOHN, S. The economic impact of the Sulfonamides on the Drug Industry. *Chemical and Engineering News* (July 1943) pp. 1159-1161.
- 37 .... The Nation's Drug Bill. *Journal of American Medical Association*, (Aug. 1953 Vol. 152, No. 18, pp. 1650-1651).
- 38 .... Prescribing of proprietaries. *Journal of American Medical Association* (Aug. 1953 Vol. 152, No. 17, pp. 1730-31).
- 39 .... Preparation of near to Sterile Calf lymph (Vaccine lymph) through the 'Streptomycin technique'. *Journal of Indian Medical Association* (May 1952, Vol. XXII, No. 8, pp. 313-315).
- 40 .... Pharmaceutical Classification. *Journal of Drug and Cosmetic Industry* (Sept. 1953).
- 41 .... Searchlight on Pharmaceutical costs. *Pharmaceutical Journal* (Feb. 1952) pp. 117-118.



सत्यमेव जयते